# Decision Memo for Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to prevent (STIs) (CAG-00426N)

## Decision Summary

The Centers for Medicare & Medicaid Services (CMS) has determined the following:

The evidence is adequate to conclude that screening for chlamydia, gonorrhea, syphilis and hepatitis B, as well as high intensity behavioral counseling (HIBC) to prevent STIs, consistent with the grade A and B recommendations by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore, CMS will cover screening for these USPSTF indicated STIs with the appropriate FDA approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the primary care physician or practitioner, and performed by an eligible Medicare provider for these services.

- Screening for chlamydia and gonorrhea:
  - Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.
  - Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.
  - Women at increased risk for STIs annually.

- Screening for syphilis:

    - Pregnant women when the diagnosis of pregnancy is known and then repeat screening during the third trimester and at delivery if high risk sexual behavior has occurred since the previous screening test.
    - Men and women at increased risk for STIs annually.

- Screening for hepatitis B:
    - Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known and then rescreening at time of delivery for those with new or continuing risk factors.

CMS will also cover up to two individual 20 to 30 minute, face to face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs, if referred for this service by a primary care provider and provided by a Medicare eligible primary care provider in a primary care setting. Coverage of HIBC to prevent STIs is consistent with the USPSTF recommendation. HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:

- education,
- skills training,
- guidance on how to change sexual behavior.

The high/increased risk individual sexual behaviors, based on the USPSTF guidelines, include any of the following:

- Multiple sex partners
- Using barrier protection inconsistently
- Having sex under the influence of alcohol or drugs
- Having sex in exchange for money or drugs
- Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea)
- Having an STI within the past year
- IV drug use (for hepatitis B only)
- In addition for men – men having sex with men (MSM) and engaged in high risk sexual behavior, but no regard to age

In addition to individual risk factors, in concurrence with the USPSTF recommendations, community social factors such as high prevalence of STIs in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis and for recommending HIBC.

High/increased risk sexual behavior for STIs is determined by the primary care provider by assessing the patient's sexual history which is part of any complete medical history, typically part of an annual wellness visit or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this decision memorandum, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

For the purposes of this decision memorandum, a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));

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# Decision Memo

TO: Administrative File: (CAG-00426N)
Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs

FROM:

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SUBJECT: Coverage Decision Memorandum for Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs

DATE: November 8, 2011

## I. Decision

The Centers for Medicare & Medicaid Services (CMS) has determined the following:

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**II. Background**

Based upon publication of updated STI screening guidelines by the USPSTF, CMS initiated this national coverage analysis (NCA) to evaluate the existing evidence on STI screenings (Screening for Human Immunodeficiency Virus (HIV) infection is already covered under certain circumstances. See §210.7 Medicare National Coverage Determination Manual) and HBIC to prevent STIs and determine if the body of evidence is sufficient for Medicare coverage under §1861(ddd).

"Despite advances in both prevention and treatment, sexually transmitted infections (STIs) remain an important cause of morbidity in the United States (Lin, Witlock, et al. 2008)." In an Institute of Medicine report in 1997, Eng and Butler stated, "Sexually transmitted diseases (STDs) are hidden epidemics of tremendous health and economic consequence in the United States (Eng and Butler 1997)." (The use of STD rather than STI in this document reflects the individual author's preference.) Eng and Butler further reported that a disproportionate burden of STD-associated complications are born by women and infants and that "a variety of women's health problems, including fertility, ectopic pregnancy, and chronic pelvic pain, result from unrecognized or untreated STDs (Eng and Butler 1997)." "Active infection with STDs during pregnancy may result in a range of serious health problems among infected infants, including severe central nervous system damage and death. Adolescents are at greatest risk of STDs because they frequently have unprotected sexual intercourse, are biologically more susceptible to infection, and are likely to have social problems that significantly increase their risk (Eng and Butler 1997)."

Representative data from the National Social Life, Health, and Aging Project (NSHAP) indicated that the majority of older adults regard sexuality as an important part of life (Lindau, Schumm, et al. 2007). "A massive and growing market for drugs and devices to treat sexual problems targets older adults (Lindau, Schumm, et al. 2007)." Lindau also reported, "Many older adults are sexually active. Sexual problems are frequent among older adults, but these problems are infrequently discussed with physicians (Lindau, Schumm, et al. 2007)." A substantial number of men and women engage in sexual activity even in the eighth and ninth decades of life (Lindau, Schumm, et al. 2007). A number of changes that affect seniors require increased attention to the impact of STDs and HIV/AIDS on this population demographic (Zagaria 2008). Lack of communication with physicians could cause high-risk behaviors to go unrecognized.

Rates of STIs in the United States exceed those in all other industrialized countries (Lindau, Schumm, et al. 2007). "Sexually transmitted infections cause a substantial economic burden –direct medical costs associated with STIs in the United States are estimated at $15 billion annually (Lindau, Schumm, et al. 2007)." In addition, the number of STD cases reported to the Centers for Disease Control and Prevention (CDC) is less than the actual number of cases occurring in the U.S. population due to incomplete diagnosis and reporting (CDC Report -Sexually Transmitted Disease Surveillance 2009).

In reviewing these figures, surveillance information re-emphasizes that risk for STIs is not confined to younger individuals. According to CDC tabulations of notifiable STIs reported by state and territorial health agencies in the United States for persons of 65 years of age or older, 3,281 incident cases of syphilis, chlamydia, gonorrhea, and hepatitis B were reported in 2008. (CDC Summary of Notifiable Diseases 2008, Table 3, p. 32 (published 2010))

The scope of this NCA will evaluate the existing evidence and determine if the body of evidence is sufficient for Medicare coverage for the following:

- Screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older nonpregnant women who are at increased risk,
- Screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk,
- Screening for gonorrhea infection in all sexually active women, including those who are pregnant, if they are at increased risk,
- Screening for syphilis infection for all pregnant women and for all persons at increased risk,
- Screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit,
- HIBC for the prevention of STIs for all sexually active adolescents and for adults at increased risk for STIs.

The scope of the NCA is limited to the USPSTF grade A and B recommendations for screening for the specific STIs which are summarized in the following chart (**U.S. Preventive Services Task Force Recommendations for STIs–link provided)**.

| | Nonpregnant women | | Pregnant women | | Men | | Date |
|---|---|---|---|---|---|---|---|
| STI | Not at increased risk | At increased risk* | Not at increased risk | At increased risk* | Not at increased risk | At increased risk** | |
| Chlamydia | | A | | B | | | June 30, 2007 |
| Gonorrhea | | B | | B | | | May 31, 2005 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Syphilis | | A | A | A | | A | July 31, 2004 |
| Hepatitis B | | | A | A | | | June 30, 2009 |

* Increased risk for pregnant and nonpregnant women is defined as high-risk sexual behavior for all STIs; as age younger than 25 years for chlamydia and gonorrhea; and as high community prevalence for chlamydia, gonorrhea, and syphilis.
** Increased risk for men is defined as high-risk sexual behavior for all STIs and as high community prevalence for syphilis.

Additionally, on October 31, 2008 the USPSTF gave a grade B recommendation for HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs.

*Chlamydia*

*Chlamydia trachomatis* (CT) STI is a leading infectious disease in the US. According to results of the National Health and Nutrition Examination Survey (NHANES) series from 1996-2006, the estimated prevalence of CT in the US is 1.6% (Wetmore et al. 2011). Such studies have found that age is a factor in CT prevalence: i.e., persons less than 25 years of age have a higher prevalence of CT than do older individuals. Although studies such as this also suggested that there is little variation in CT STI prevalence by gender, surveillance studies (CDC 2010B) have concluded that gender, as well as age and other demographic factors, are associated with prevalence.

Most CT infections are transmitted by sexual activity. Certain sexual behaviors are known to be more risky for transmission of CT and other STIs. Examples of these risky behaviors include having multiple sexual partners; substance abuse; or failure to use barrier protection during sexual activity. CT STIs are often asymptomatic. Asymptomatic infection from CT STI is thought to be present in from 1-25% of infected men and up to 70% of infected women (APHA 2008). Symptoms, if any, vary by gender; in men, symptoms of discharge, itching, and burning on urination are frequent; in women, symptom of discharge, or irritation referable to the urethra, anus, or pelvis predominate. Reinfection by CT is common. Untreated CT STI infections may persist for months.

CT infection has been associated with concomitant *Neisseria gonorrheae* (NG) STI as well as with increased risk of HIV infection. The frequency of CT and NG co-infections has led to recommendations for combined testing and treatment for individuals in whom either infection is detected (CDC 2010A).

In 2009, CDC compiled 1,244,180 incident CT STI cases from all states across the US in all age groups. This represents a reported incident CT STI rate of 409.2 / 100,000 (CDC 2010B). Compared with that of 1990, the 2009 annual rate of reported incident CT STIs is 2.5 times higher (from 160.2 (1990) to 409.2 (2009) / 100,000). Incident CT STI rates are increasing across most population groups from 2000 through 2009 (CDC 2010B).

The proportion of sexually active females between the ages of 15 and 25 screened for chlamydial infection annually is a quality measure by US health plans, based on a Healthcare Effectiveness Data and Information Set (HEDIS) recommendation. In 2008, 44.7% of all eligible adolescents and young women were screened for CT STI (up from 25.4% screened in 2000). The 2008 overall percentage of women screened for CT STI represented 585 reporting health plans and more than 2,700,000 young women (CDC Chlamydia Screening Percentages: http://www.cdc.gov/std/chlamydia/female-enrollees-00-08.htm).

In older age groups, rates of CT STI cases tend to be lower. Among Americans 55-64 years of age, infection rates for Chlamydia were eleven/100,000 and nine/100,000 in men and women, respectively, in 2009; and the rates were two/100,000 and three/100,000, respectively, in men and women greater than 64 years of age (CDC 2010B).

The USPSTF recommends screening all sexually active women aged 24 years or younger, nonpregnant and pregnant, and all women, nonpregnant or pregnant, who are at increased risk for chlamydia with a Grade A or B (USPSTF Recommendation Screening for Chlamydia).

*Gonorrhea*

Gonorrhea, a sexually transmitted infection due to the bacterium *N. gonorrheae* (NG STI), continues to be an important cause of infectious disease in the U.S. according to a widely used public health reference on infectious diseases (APHA 2008).

> " … In females, infection is followed by the development of mucopurulent cervicitis, often asymptomatic, although some women have abnormal vaginal discharge and vaginal bleeding after intercourse. In about 20% there is also uterine invasion, often timed with menstruation, with resultant endometritis, salpingitis or pelvic peritonitis and subsequent risk of infertility and ectopic pregnancy. … In females and homosexual males, pharyngeal and anorectal infections are not uncommon. While infection of the pharynx and rectum are often asymptomatic, anorectal infections may cause pruritus, tenesmus, and discharge. Septicemia (also known as disseminated gonococcal infection) may occur in 0.5% - 1% of all gonococcal infections, and can result in arthritis, skin lesions, and (rarely) endocarditis and meningitis (APHA 2008)."

In women, NG STI is a leading cause of pelvic inflammatory disease (PID).

NG STI prevalence estimates are based on data from gonorrhea screening results available from family planning clinics, and ranged from 0.0% to 3.4% among women aged 15–24 years in 2009 (CDC 2010B). In 2009, 301,174 reported incident cases of gonorrhea were reported in the United States, or a rate of 99.1/100,000. The 2009 rate is a 10.5% decrease from the rate of 110.7/100,000 in 2008 (CDC 2010B, Figure 14, Table 1). Since 1996 reported incident NG STI rates in men have been similar to those in women. In 2009, reported incident NG STI rates were 105.5/100,000 in women and 91.9/100,000 in men (CDC 2010B).

Data from 2009 showed that reported incident NG STI rates were highest among adolescents and young adults. In 2009, women aged 15–19 and 20–24 years had the highest reported incident NG STI rates (568.8/100,000 and 555.3/100,000, respectively). Among men, the highest reported incident NG STI rate was in the 20–24 year age group (407.5/100,000). During 2005 – 2009, reported incident NG STI rates decreased in all age groups. The largest decreases were in those aged 40–44 years (33.4%), 65 years or older (33.3%), and 35–39 years (29.8%). CDC surveillance data indicate that gender-specific rates of reported incident NG STI cases in individuals of 65 years of age or older were lower than for any other age group: 2.7/100,000 (males) and 0.5/100,000 (females) (CDC 2010B, Table 20).

In 2009, as in previous years, reported incident NG STI rates varied greatly among different regions and states. In 2009, the South had the highest rate (133.2/100,000) among the four regions of the country. Rates in the South and Midwest remained higher than rates in the Northeast and West. State-to-state variation was substantial, with 2009 rates for all age groups ranging from a minimum of 7.2/100,000 in Idaho to a maximum of 246.4/100,000 in Mississippi (CDC 2010B, Table 14).

NG STIs have been associated with concomitant CT STIs as well as with increased risk of HIV infections. The frequency of CT and NG co-infections has led to recommendations for combined testing and treatment for individuals in whom either infection is detected (CDC 2010A).

The USPSTF recommends screening for NG STI in all women, nonpregnant and pregnant, who are at increased risk (that is, if they are younger than 25 years of age or have other individual or population risk factors) with a Grade B (USPSTF Recommendation Screening for Gonorrhea).

*Syphilis*

Syphilis is an infection caused by the spirochetal bacterium *Treponema pallidum*. The infection may progress through four stages: primary syphilis (during the first few months and weeks after exposure); secondary syphilis (during the following months to about a year); latent syphilis (of variable length, from several to many years); and tertiary (end-stage) syphilis. The infection can be clinically silent in primary and secondary syphilis, but may after long periods of latency involve skin, bone, internal organs, especially the central nervous system and the cardiovascular system. In primary and secondary syphilis ('early syphilis') the infectious agent *T. pallidum* is present in the ulcers or exudates of skin and mucous membranes lesions, but can also spread through the bloodstream (APHA 2008). Uninfected persons can be exposed to the infectious agent through contact with infectious skin or mucous membrane lesions, primarily during sexual contact (APHA 2008). An infected mother may transmit the infectious agent to the fetus transplacentally, initiating a congenital syphilis infection (APHA 2008). Rarely, infection occurs due to transfusions of blood from a donor in the early stages of infection (APHA 2008). Ulcers in early syphilis may provide an access for the human immunodeficiency virus to the bloodstream, and thereby syphilis is thought to facilitate HIV transmission (WHO Fact Sheet 2007). Individuals may be co-infected either with syphilis and HIV disease, or with syphilis and another STI (APHA 2008).

Symptoms and signs of primary syphilis usually appear in about three weeks, although these may be imperceptible to the infected individual. These early symptoms and signs may resolve without treatment. Secondary syphilis may involve the CNS or skin with a widespread rash, or may be symptomatic. The latent stage of the infection is usually asymptomatic. Signs of tertiary syphilis may include disabling or life-threatening lesions of the aorta and the severe central and peripheral neurologic disturbances of neurosyphilis. Congenital syphilis may result in stillbirth or abortion, or in low-birth weight infants with malformations or lesions of teeth, bone, and skin, as well as deafness and severe mental disability (APHA 2008).

In a review of data on reported syphilis in the US (Aral et al. 2007), investigators from the CDC noted that incidence of primary and secondary syphilis dropped to record low levels by 2000. However, rates among men (but not women) increased in recent years (2001 – 2005). Public health responses to control syphilis focus both on prevention and on early detection and treatment for those at increased risk for syphilis exposure. CDC has issued a series of risk-based recommendations for reporting and public health follow-up of incident syphilis cases, for interpretation of syphilis serologic test results, and for antibiotic treatment (CDC 2010B).

The USPSTF recommends screening all pregnant women for syphilis and all other persons (women and men) who are at increased risk with a Grade A (USPSTF Recommendation Screening for Syphilis 2004).

*Hepatitis B*

Hepatitis B is a serious viral infection of the liver. Its agent, HBV, is present in blood and certain other body fluids of infected persons. Uninfected persons can be exposed to HBV if blood or certain other body fluids from an infected person come into contact with mucous membranes or wounds, or due to parenteral injection of HBV-contaminated blood or body fluids. HBV infection can be transmitted during sexual activity or through perinatal exposure of a newborn to contaminated body fluids of its mother. (APHA 2008)

Symptoms and signs of HBV infection appear in 30-50% of infected adults, usually in an insidious manner six weeks to six months after exposure. Symptoms can include anorexia, vague abdominal discomfort, nausea, vomiting, and jaundice. An estimated 5-10% of those infected as adults do not resolve their infections, but instead develop chronic hepatitis B (CHB). In contrast, of those infected at birth, 90% develop CHB. From 15 – 25% of those with CHB progress over decades to cirrhosis and liver failure and/or to hepatocellular carcinoma (HCC). Cirrhosis and liver failure, as well as HCC, each carry a high mortality rate (APHA 2008).

A review of the CDC surveillance data (CDC 2010) shows that, over the last 25 years, reported HBV infections decreased by 85% (from 26,115 during 1984 to 4,033 for 2008). Nevertheless, an estimated 1.25 million US residents have CHB, and of these an estimated 2000 – 4000 die each year due to CHB sequelae (Weinbaum 2009).

The USPSTF recommends screening all pregnant women for hepatitis B at the first prenatal visit with a Grade A (USPSTF Recommendation Screening for Hepatitis B Infection 2004, reaffirmed in 2009).

**III. History of Medicare Coverage**

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" if certain statutory requirements are met. Our regulations provide:

*§410.64 Additional preventive services*

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.
(3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

*Chlamydia*
Currently, screening for chlamydia is not covered.

*Gonorrhea*
Currently, screening for gonorrhea is not covered.

*Syphilis*
Currently, screening for syphilis is not covered.

*Hepatitis B*
Currently, screening for hepatitis B viral infection is not covered.

*HIBC to prevent STIs*
Currently, HIBC to prevent STIs is not covered.

**IV. Timeline of Recent Activities**

| | |
|---|---|
| February 24, 2011 | CMS initiates opening a NCA for screening for STIs and HIBC to prevent STIs. Initial 30-day public comment period begins. |
| March 26, 2011 | Initial public comment period closed. |
| August 10, 2011 | Posted PDM. |
| September 9, 2011 | Second public comment period closed. |

**V. Food and Drug Administration (FDA) Status**

Diagnostic laboratory tests are regulated by the FDA. Numerous laboratory tests that can detect the presence of STIs are FDA approved/cleared and available. The FDA In Vitro Diagnostics database provides specific information on the approved tests for each of the STIs under consideration in this NCA.

*Chlamydia and Gonorrhea*

Tests to detect gonorrhea are based on recognition of specific DNA or ribosomal RNA sequences for *Neisseria gonorrheae*; however, other available techniques are based on different approaches to organism detection, e.g., immunoassay or culture. Tests to detect CT STIs include those based on similar principles of DNA or RNA sequence recognition for *Chlamydia trachomatis*.

A search performed by CMS staff in June 2011 of the FDA's Office of the In Vitro Diagnostics (OIVD) database for CT and NG testing revealed dozens of cleared test devices. These products, including those offering detection of both CT and NG, were initially approved/cleared between 1982 and 2010.

*Syphilis*

The FDA has approved tests to detect antibodies to *T. pallidum* which develop at various stages during syphilis. Test types include both treponemal (in which the test kits include *T. pallidum* specific antigens to bind to any antibodies in the sample) and non-treponemal (in which any antibodies bind to non-treponemal antigens (e.g., cardiolipin) known to react with sera from persons with syphilis).

A search performed by CMS staff during June 2011 using the FDA's OIVD database for syphilis testing revealed more than 60 currently cleared products. Some of these products, initially approved between 1993 and 2010, are based on serological or immunoassay techniques. Some are available for automated immunoassay instrument systems. Some specifically assess IgG antibodies to syphilis.

*Hepatitis B*

The FDA has approved tests to detect hepatitis B viral antigens, viral nucleotide sequences, and antibodies to HBV antigens. The most commonly used of these tests detects a protein antigen HBsAg indicating the presence of infectious viral particles in body fluids by infected cells. The test is most often performed on serum samples of the person being tested.

A search performed by CMS staff during June 2011 using the FDA's OIVD database for HBsAg diagnostic tests revealed numerous currently FDA-approved products. These products initially approved between 1999 and 2006, are based on immunoassay techniques and are available for automated immunoassay instrument systems.

**VI. General Methodological Principles**

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B of the Medicare program.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

## VII. Evidence

### A. Introduction

Consistent with §1861(ddd)(1)(A) and 42 CFR 410.64(a)(1), additional preventive services must be reasonable and necessary for the prevention or early detection of illness or disability. With respect to evaluating whether screening tests conducted on asymptomatic individuals are reasonable and necessary, the analytic framework involves consideration of different factors compared to either diagnostic tests or therapeutic interventions. Evaluation of screening tests has been largely standardized in the medical and scientific communities, and the "value of a screening test may be assessed according to the following criteria:

i. *Simplicity*. In many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel.
ii. *Acceptability*. As screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects.
iii. *Accuracy*. The test should give a true measurement of the attribute under investigation.
iv. *Cost*. The expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure.

v. *Precision (sometimes called repeatability)*. The test should give consistent results in repeated trials.
vi. *Sensitivity*. This may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation.
vii. *Specificity*. This may be defined as the ability of the test to give a negative finding when the individual screened does not have the disease or abnormality under investigation (Cochran and Holland 1971)."

As Cochrane and Holland (1971) further noted, evidence on health outcomes, i.e., "evidence that screening can alter the natural history of disease in a significant proportion of those screened", is important in the consideration of screening tests since individuals are asymptomatic and "the practitioner initiates screening procedures (Cochran and Holland 1971)."

Four of the seven criteria cited above (Cochrane and Holland 1971) as reasonable and necessary for screening tests (i.e., accuracy, precision, sensitivity and specificity) reflect a screening test's ability to minimize the harm of testing inaccuracy, especially from false positive or false negative results. Screening test compliance with these criteria is within the scope of FDA review of in-vitro diagnostic devices and the FDA has only reviewed evidence on the approved label indications for these tests.

With respect to evaluating whether high intensity behavioral counseling should be an additional preventive benefit, we consider whether there is evidence that receiving such services is associated with changes in risk-related behaviors providing improved outcomes.

**Primary Care and USPSTF Recommended Preventive Services**

The USPSTF's recent recommendations state that its evidence supports use of the primary care setting for clinical preventive care services, including those discussed in this decision memorandum. From the Preface to 2010-2011 USPSTF Clinical Preventive Services guide (available at http://www.ahrq.gov/clinic/pocketgd1011/pocketgd1011.pdf, pp. v-vi):

**"Preface**
Since being codified by Congress in 1984, the U.S. Preventive Services Task Force (USPSTF) has been fulfilling its charge to conduct rigorous reviews of research evidence to create evidence-based recommendations for preventive services that should be provided in the primary care setting … Our Procedure Manual, which can be found at http://www.USPreventiveServicesTaskForce.org/uspstf08/methods/procmanual.htm, outlines our updated process for evaluating the quality and strength of the evidence for a service, determining the net health benefit (benefit minus harms) associated with the service, and judging the level of certainty that ***providing these services in primary care will realize the expected level of benefit*****."(Emphasis added by CMS.)**

The Institute of Medicine (IOM) has provided a definition of primary care based on the function which states: "Primary care is the provision of *integrated, accessible health care services* by clinicians who are *accountable* for addressing a large majority of personal health care needs, developing a *sustained partnership with patients*, and practicing in the *context of family and community* (IOM. *Primary Care: America's Health in a New Era* 1996)." In discussing the value of primary care, one of the elements cited supporting this definition is that primary care "…opens opportunities for disease prevention and health promotion as well as early detection of disease… (IOM *Primary Care: America's Health in a New Era* 1996)." The Agency for Health Research and Quality (AHRQ) has adopted the IOM definition of primary care in their primary care practice based research networks (PBRNs)(http://pbrn.ahrq.gov/portal/server.pt/community/practice_based_research_networks_%28pbrn%29__about/852 ).

Many preventive services are discussed within the context of the primary care setting and the USPSTF reviews preventive services that should be provided in the primary care setting. Primary care providers are thought of as the initial contact for patients within a complicated health system. Primary care providers are often identified as the conduit for identifying the need for preventive services by assessing the patient's individual risk factors and developing a comprehensive prevention plan that directs patients in a coordinated manner to appropriate services to address their individual health risks and provide the most efficient utilization of health care services.

**B. USPSTF Grade Definitions (**parentheses and brackets are the USPSTF's)

"The U.S. Preventive Services Task Force (USPSTF) assigns one of five letter grades to each of its recommendations (A, B, C, D, I). The USPSTF changed its grade definitions based on a change in methods in May 2007)."

**Grade Definitions After May 2007**

"The USPSTF updated its definitions of the grades it assigns to recommendations and now includes "suggestions for practice" associated with each grade. The USPSTF has also defined levels of certainty regarding net benefit. These definitions apply to USPSTF recommendations voted on after May 2007.

| Grade | Definition | Suggestions for Practice |
|---|---|---|
| **A** | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer or provide this service. |
| **B** | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| **C** | The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. | Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. |

| Grade | Definition | Suggestions for Practice |
|---|---|---|
| **D** | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| **I Statement** | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. | Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms. |

**Levels of Certainty Regarding Net Benefit**

| Level of Certainty | Description |
|---|---|
| **High** | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| **Moderate** | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: |

| Level of Certainty | Description |
|---|---|
| | • The number, size, or quality of individual studies.<br>• Inconsistency of findings across individual studies.<br>• Limited generalizability of findings to routine primary care practice.<br>• Lack of coherence in the chain of evidence.<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| **Low** | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:<br><br>• The limited number or size of studies.<br>• Important flaws in study design or methods.<br>• Inconsistency of findings across individual studies.<br>• Gaps in the chain of evidence.<br>• Findings not generalizable to routine primary care practice.<br>• Lack of information on important health outcomes.<br><br>More information may allow estimation of effects on health outcomes. |

* The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service."

**Grade Definitions Prior to May 2007**

"The definitions below (of USPSTF grades and quality of evidence ratings) were in use prior to the update and apply to recommendations voted on by the USPSTF prior to May 2007.

'A' – Strongly Recommended: The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

'B' – Recommended: The USPSTF recommends that clinicians provide [the service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

'C' – No Recommendation: The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

'D' – Not Recommended: The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

'I' – Insufficient Evidence to Make a Recommendation: The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined."

**Quality of Evidence** (prior to May 2007)

The USPSTF [prior to May 2007] graded the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

**Good:** Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

**Fair:** Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

**Poor:** Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

**C. U.S. Preventive Services Task Force Recommendations for STIs–(link provided)**

Each of the STI screenings under consideration, as well as HIBC for the prevention of STIs, has received an A or B recommendation for the USPSTF. The evidence supporting these recommendations is considered and summarized in section VII.F of this document.

## D. Determining High/Increased Risk for Screening for STIs and HIBC to Prevent STIs

The USPSTF provides the following information on determining who meets the increased risk or high-risk classification.

> For nonpregnant women, the two main considerations a physician should use to determine if a patient has an increased risk of STIs are high-risk sexual behavior (e.g., having multiple current partners, using barrier protections inconsistently, having sex while under the influence of alcohol or drugs, having sex in exchange for money or drugs) and age. Younger women have a higher risk for STIs than older women because younger women have more new sex partners and because of the relative immaturity of their immune systems and the presence of columnar epithelium on the adolescent exocervix.
>
> For pregnant women, the same factors should be used that determine a nonpregnant women's risk status (high-risk sexual behavior and age).
>
> For men, high-risk sexual behavior is the consideration. "In men, as in women, it is important that physicians take a thorough sexual history to assess if the patient engages in high-risk sexual behavior."
>
> "Rather than considering each recommendation separately, physicians can cluster STI screening at the time of a periodic health examination." (USPSTF Recommendations for STI Screening)

Increased risk for HIBC to prevent STIs is similar to the increased risk population for screening for STIs. All sexually active adolescents are at increased risk for STIs and adults who have multiple sex partners and /or who have or have had an STI within the past year. In addition, in communities or populations with high rates of STIs, all sexually active patients in non-monogamous relationships may be considered at increased risk (Lin, Whitlock, et al. 2008 AHRQ Evidence Synthesis Number 64).

## E. Literature Search

In addition to the prerequisite USPSTF recommendations, CMS must consider not only whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, but whether the service is appropriate for individuals entitled to benefits under part A or enrolled under part B of the Medicare program.

The details of the literature search for each of the topics under consideration are described at the beginning of the each specific topic under the discussion of the evidence section.

**F. Discussion of evidence**

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of screening for STIs and HIBC to prevent STIs for Medicare patients.

***Chlamydia and Gonorrhea***

*(Note: Some of the evidence, screening guidelines, test procedures and treatments address chlamydia and gonorrhea together, therefore we have combined them in our evidence review and analysis.)*

A search of relevant published articles was conducted by CMS staff in March and April 2011, using the search terms "chlamydia", "gonorrhea", and "screening", limited to clinical studies published within the last ten years about the effects of CT and/or NG screening interventions on behavioral and/or health outcomes. In addition, articles cited in the bibliography of any relevant USPSTF recommendation statement(s) were sought. Forty-four citations were found and reviewed at the abstract level. Numerous studies in which CT and/or NG STI screening was an outcome, rather than an intervention, were judged not relevant to this topic. Two systematic reviews (Meyers 2007, Glass 2005) cited by USPSTF recommendations in 2005 and in 2007 for NG and CT screening and one systematic review of test performance (Cook 2005) are summarized under the External TA section below. In addition, three RCTs (Oakeshott 2010, Scholes 2006, Østergaard 2000) and one cohort study (Sznitman 2010) were judged relevant to this topic and are summarized below under the Internal TA section. In each section below, articles are listed below in reverse chronological order, and then alphabetically by first author.

**1.a Questions:**

CMS analyzed the following questions:

- Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea is recommended with a grade of A or B by the USPSTF?
- Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women at increased risk for chlamydia and/or gonorrhea is reasonable and necessary for the prevention or early detection of illness or disability?
- Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women at increased risk for chlamydia and/or gonorrhea is appropriate for Medicare beneficiaries?

**2.a External technology assessments (TA)**

In this evidence update report for the 2007 USPSTF recommendations about CT STI screening, the authors examined a 2001 systematic review of evidence for effectiveness of CT screening (Nelson and Helfand 2001). AHRQ staff conducted a systematic review of the published literature from July 2000 through July 2005 as the basis for this evidence update, focusing on key questions such as: "Does screening for chlamydial infection in women reduce adverse health outcomes?" They found one article (Østergaard et al. 2000) (summarized below (section VII.F.3.a)) that used a cluster-randomized trial of CT screening for high school girls and found significant effects on prevalence of chlamydial infection and reported cases of PID after a one year followup. The intervention and control groups were designed to be home sampling versus clinician sampling. However, the rates of acceptance by each group were so widely different 867/928 (93%) were tested in the home sampling group and 63/833 (8%) were tested in the control group) that this trial could be interpreted as more reflective of screening vs. no screening rather than setting (home vs. physician's office). The study's outcome assessments for the two groups therefore amounted to a cluster-randomized controlled trial of the effects of screening itself, rather than site of screening services, on subsequent infection or PID as outcomes. The authors concluded that the evidence base supporting screening for chlamydial infection has not expanded greatly since the prior USPSTF recommendation.

*Glass N, Nelson HD, Villemyer K. Screening for Gonorrhea: Update of the Evidence for the U.S. Preventive Services Task Force. Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, Rockville, MD. May 2005. Publication No. 05-0579-B.*

In this evidence update report for the USPSTF 2005 Recommendation about NG STI screening, the authors examined published evidence about the effectiveness of screening for NG STI in asymptomatic sexually active men and women including adolescents and pregnant women. They found articles from the MEDLINE® database from January 1966 through July 2004, of which 310 articles were selected for review at the full-text level. The authors found no new evidence about the effectiveness of population screening to improve health outcomes. These authors also reviewed the effects of screening for NG on adverse maternal or pregnancy outcomes. Two post-1996 studies were identified with new information on third trimester screening. One was a retrospective chart review study of the effect of third trimester re-screening after an initially negative initial prenatal screen for NG. About 2.5% of 751 participants had positive NG screening results only in the third trimester. In another study, 4% of 542 women in prenatal care were positive in the third trimester for NG (and CT) after initial negative tests. The authors concluded that:

- Age is the strongest predictor of gonococcal infection (< 25 years). Additional risk factors include African American race, having multiple sex partners or an infected sex partner, inconsistent use of barrier contraceptives, previous or coexistent STDs, douching, use of drugs, and history of incarceration.
- Contextual risk factors include sexual networks, sexual mixing within a community or neighborhood with high prevalence of STDs, and residence in a community with limited social capital or markers of physical deterioration.
- Screening all women aged 18-31 years is more cost-effective than selective screening even when the combined prevalence of gonorrhea and chlamydia is 7%-17.5%. For men, standard practice (e.g., history and examination) is more cost-saving than enhanced screening strategies.
- No studies were found providing evidence about the effectiveness of screening in preventing disease complications and transmission.

**Test Performance**

*Cook RL, Hutchison SL, Østergaard L, Braithwaite RS, Ness RB. Systematic review: non-invasive testing for CT and NG. Ann Intern Med. 2005 Jun 7; 142: 914-25.*

In this systematic review, the authors examined evidence from studies published from 1991 to 2004 evaluating any of three commercially available NAATs for CT and NG in urine specimens. The results showed pooled study specificities for CT and NG STI exceeding 97% for both men and women. The pooled study sensitivities for the polymerase chain reaction, transcription-mediated amplification, and strand displacement amplification assays, respectively, were 83.3%, 92.5%, and 79.9% for chlamydial infections in women; 84.0%, 87.7%, and 93.1% for chlamydial infections in men; and 55.6%, 91.3%, and 84.9% for gonococcal infections in women. The pooled specificity of polymerase chain reaction to gonococcal infections in men was 90.4%. The authors acknowledged that few of the reviewed studies reported information on performance characteristics of such tests from asymptomatic patients or low-prevalence groups. The authors concluded that based on these studies, for the three commercially available CT detection methods using NAATs, the sensitivity of non-invasive (urine)-based tests was nearly identical to those tests performed on invasively obtained samples (endocervical or urethral swabs). No non-NAAT method was sufficiently sensitive to be recommended for use on urine samples. However, for the PCR assay for NG, the sensitivity and specificity were significantly lower when used on urine samples rather than cervical samples. These authors called for additional research on both CT and NG tests on urine samples, especially in low-risk and asymptomatic populations.

**Summary of Evidence for USPSTF Recommendation**

In their 2005 recommendation statement, USPSTF summarized the rationale for NG screening:

"Women with asymptomatic gonorrhea infection have high morbidity due to pelvic inflammatory disease, ectopic pregnancy, and chronic pelvic pain. Pregnant women with gonorrhea infection are at risk for preterm rupture of membranes, preterm labor, and chorioamnionitis. There is fair evidence that screening tests can accurately detect gonorrhea infection and good evidence that antibiotics can cure gonorrhea infection. There is fair evidence that screening pregnant women at high risk for gonorrhea, including women at high risk because of younger age, may prevent other complications associated with gonococcal infection during pregnancy, such as preterm delivery and chorioamnionitis. Potential harms of screening and treatment for gonorrhea include false-positive test results, anxiety, and unnecessary antibiotic use. There is insufficient evidence (due to a lack of studies) to quantify the magnitude of these potential harms. The USPSTF judges the magnitude of the potential harms to be small. The USPSTF concludes that the benefits of screening women at increased risk for gonorrhea infection outweigh the potential harms (USPSTF 2005)."

In their 2007 recommendation statements, USPSTF provided the rationale for CT STI screening:

"Chlamydial infection is the most common sexually transmitted bacterial infection in the United States. In women, genital chlamydial infection may result in urethritis, cervicitis, pelvic inflammatory disease (PID), infertility, ectopic pregnancy, and chronic pelvic pain. Chlamydial infection during pregnancy is related to adverse pregnancy outcomes, including miscarriage, premature rupture of membranes, preterm labor, low birth weight, and infant mortality. … The USPSTF found fair evidence that nucleic acid amplification tests (NAATs) can identify chlamydial infection in asymptomatic men and women, including asymptomatic pregnant women, with high test specificity. In low prevalence populations, however, a positive test is more likely to be a false positive than a true positive, even with the most accurate tests available (USPSTF 2007)."

The 2007 USPSTF recommendation for CT STI screening pointed out its benefits in two specific groups of women:

"*Non-pregnant women at increased risk*. There is good evidence that screening for chlamydial infection in women who are at increased risk can reduce the incidence of PID. The USPSTF concluded that the benefits of screening women at increased risk are substantial.
"*Pregnant women at increased risk*. There are no studies evaluating the effectiveness of screening for chlamydial infection in pregnant women who are at increased risk. The USPSTF, however, found the following:

1. Screening identifies infection in asymptomatic pregnant women.
2. There is a relatively high prevalence of infection among pregnant women who are at increased risk.
3. There is fair evidence of improved pregnancy and birth outcomes for women who are treated for chlamydial infection.

"The USPSTF concluded that the benefits of screening pregnant women who are at increased risk are substantial." (USPSTF 2007)

Other points of the USPSTF recommendations of 2005 and 2007 included:

- NAATs can be used with urine and vaginal swabs, enabling screening when a pelvic examination is not performed.
- Appropriate treatment guidelines for both CT and NG STIs were available at the time the USPSTF 2005 and 2007 recommendations were published.
- For pregnant women in a high risk group for NG STI, screening is recommended at the first prenatal visit. For pregnant patients who are at continued risk, and for those who acquire a new risk factor, a second screening should be conducted during the third trimester. The optimal interval for screening in the non-pregnant population is not known. (USPSTF 2005)
- For pregnant women at increased risk for CT STI, screening is recommended at the first prenatal visit. For pregnant women who remain at increased risk and for those who acquire a new risk factor, such as a new sexual partner, a screening should be conducted during the third trimester. The optimal interval for screening for nonpregnant women is unknown. The CDC recommends at least annual screening for women at increased risk. (USPSTF 2007)
- Risk factors for gonorrhea include a history of a previous gonorrhea infection, other sexually transmitted infections, new or multiple sexual partners, inconsistent use of barrier protection, sex work, drug use, and under the age of 25 and sexually active. Risk factors for pregnant women are the same as for non-pregnant women (USPSTF 2005)
- Risk factors for chlamydia include age (under the age of 25), multiple sexual partners, having a new sexual partner or an infected sexual partner, inconsistent use of barrier protection and a history of STI (UDPSTF 2007).

**3.a Internal TA**

**Evidence summary**

*Oakeshott P, Kerry S, Aghaizu A, Atherton H, Hay S, Taylor-Robinson D, et al. RCT of screening for CT to prevent pelvic inflammatory disease: the POPI (prevention of pelvic infection) trial. BMJ. 2010 Apr 8; 340: c1642 (e-published April 8, 2010).*

These investigators conducted a randomized controlled trial (RCT) to find out if screening combined with treatment of CT infection reduces PID incidence in the following twelve months. The study participants (n=2529) were sexually active female students, 16-27 years of age (average: 20.9 years), recruited by female research staff from common rooms, bars, and lecture theatres at 20 London universities and further education colleges. All participants completed a questionnaire at baseline, submitted self-collected vaginal swabs for CT testing, were informed of symptoms and signs of CT infection and were instructed to seek care if they were concerned about any symptoms during the followup period. Of the participants ('screened women'), 1259/2529 were randomly assigned to immediate testing by NAAT and (if appropriate) treatment. Of the participants ('controls'), 1270 were randomized to specimen storage and deferred testing. Ninety-four percent of participants (2377/2529) underwent followup after one year. Results showed that incident PID occurred in 1.3% of screened women, compared to 1.9% of controls (relative risk 0.65, 95% CI 0.34 – 1.22), among the 2377/2529 (94%) participants who presented for twelve-month followup. Most episodes of PID occurred in women who tested negative for CT infection at baseline (30/38). The authors concluded that the effectiveness of chlamydia screening in preventing PID over the twelve months after screening may have been overestimated. They suggested that more frequent testing might be needed in high-risk individuals.

*Sznitman SR, Carey MP, Vanable PA, DiClemente RJ, Brown LK, Valois RF, et al. The impact of community-based sexually transmitted infection screening results on sexual risk behaviors of African American adolescents. J Adolesc Health. 2010 Jul; 47(1): 12-9.*

In this study of a cohort of African-American adolescents in the US, the investigators assessed the effect of STI screening (for CT, NG, and *Trichomonas vaginalis*) on sexual behavior at six months' followup of those reporting sexual experience before or during the trial (n=636). In the study population, those testing negative for any STI received no further intervention related to their test result. Those testing positive for any STI received treatment with a single dose of antimicrobial therapy and counseling according to 2006 CDC STD treatment guidelines. Behavioral outcomes assessed at three and six months' followup included number of sex partners and unprotected sexual contacts. Results showed that 52% of participants were female. At baseline, 6.6% tested positive for at least one STI; females were more likely than males to test STI-positive. Those testing STI-positive were more likely ($p < 0.01$) to report multiple vaginal sex partners and unprotected sex. The investigators also found that during the followup period, there was a 44% reduction at six months in number of vaginal sex partners in STI-positive participants. In contrast, STI-negative participants increased their number of vaginal sex partners by 32% during the six-month followup period, although this was found not to be significant. There was also a significant reduction in unprotected sex occurrences. Also, at six months, eight of 42 (19%) of STI-positive participants at baseline were re-infected on repeat STI testing. In addition, 4.3% of those testing STI-negative at baseline tested STI-positive at six months. The authors acknowledged that the study included a relatively brief followup period (of six months); that the quality of counseling provided to STI-positive participants was not assessed; and that the experimental design did not allow for assessment of possible interaction of STI-screening and STI-counseling interventions. The authors concluded that CT and NG screening reduced self-reported STI risk behaviors among those who were STI-positive at screening.

*Østergaard L, Andersen B, Møller JK, Oleson F. Home sampling versus conventional swab sampling for screening of Chlamydia trachomatis in women: a cluster-randomized 1-year follow-up study. Clin Infect Dis. 2000; 31: 951–7.*

This article about a block randomization study, cited in the evidence update report (Meyers et al. 2007) for the USPSTF 2007 CT screening recommendation, compared the efficacy of a screening program for urogenital CT infections based on home sampling with that of a screening program based on conventional swab sampling performed at a physician's office. Female students at 17 high schools in the county of Aarhus, Denmark, were divided into a study group (tested by home sampling) and a control group (tested in a physician's office). These investigators assessed the number of new infections and the number of subjects who reported being treated for pelvic inflammatory disease (PID) at 1 year of follow-up. Results showed that 443 (51.1%) of 867 women (median age = 17 years) in the intervention group and 487 (58.5%) of 833 women (median age = 17 years) in the control group were available for follow-up. Thirteen (2.9%) and 32 (6.6%) new CT infections were identified in the intervention group and the control group, respectively (Wilcoxon exact value, *P* =.026). Nine (2.1%) women in the intervention group and 20 (4.2%) in the control group reported being treated for PID (*P* = .045). The authors concluded that screening is associated with a lower prevalence of CT infections and a lower proportion of reported cases of PID.

*Scholes D, Stergachis A, Heidrich FE, Andrilla H, Holmes KK, Stamm WE. Prevention of PID by screening for cervical chlamydial infection. N Engl J Med 1996 May 23; 334(21): 1362-6.*

These investigators conducted an RCT within a managed care organization (MCO) population in Washington State, US, to determine if screening for cervical chlamydial infection prevented pelvic inflammatory disease. All women enrollees in the MCO were eligible to participate. Participants were randomized to the screening group or the control group (who received usual care from their providers) with the intended proportion of screening to control participants being 1:2. Of 2607 eligible women, 1009 were assigned to the screening group, and 1598 were assigned to the control group. The average age in both groups was 22 years. Participants in the screening group (645) were tested for CT (by ELISA and cell culture), and 44/645 (7%) were found to be positive for CT. These 44 participants were treated for CT by their primary care provider. At one-year follow-up, based on either follow-up questionnaires completed by participants or by review of diagnoses in the MCO electronic records, 42 participants had confirmed cases of PID in the follow-up period; nine in the screening group and 33 in the control group. In terms of woman-months of followup, the incidence of PID in the screening group was eight per 10,000 women-months, and 18 per 10,000 women-months (RR 0.44 (95% CI of 0.20 – 0.90)). Adjustment for race/ethnic group, gravidity, douching, marital status, and age did not substantially alter the reduction in PID risk associated with screening. The authors concluded that the strategy of screening and treating women identified by self-report of risky sexual behaviors was associated with reduced incidence of PID.

***Syphilis***

A search of relevant published articles was conducted by CMS staff in March and April 2011, using the search terms "syphilis" and "screening", limited to clinical studies published within the last ten years about the effects of syphilis screening interventions and sexual behavior or sexual health outcomes. In addition, articles cited in bibliography of any relevant USPSTF recommendation statement(s) were sought. Forty-two citations were found and reviewed at the abstract level. Numerous studies in which syphilis screening was an outcome, rather than an intervention, were judged not relevant to this topic. One systematic review about the use of syphilis screening during pregnancy and prevention of stillbirth (Menezes 2009) is summarized under the External TA section below (VII.F.2.b). In addition, six articles, including one large retrospective cohort study (Cheng 2007), two surveys using national population or random Medicare beneficiaries samples (Reece 2010, Smith 2009), one retrospective survey of testing results for syphilis using stored serum samples (Geusau 2005), and two non-clinical studies (Jena 2010, Owusu-Edusei 2010) were judged relevant to this topic and are summarized below under the Internal TA section (VII.F.3.b). In each section below, articles are listed in reverse chronological order, and then alphabetically by first author.

**1.b Questions**

- Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is recommended with a grade of A or B by the USPSTF?
- Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is reasonable and necessary in the prevention or early detection of illness or disability?
- Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is appropriate for Medicare beneficiaries?

**2.b External TA**

One systematic review (Menezes et al. 2009) examined the role of syphilis screening and treatment of pregnant women and its effect in preventing stillbirths

*Menezes EV, Yakoob MY, Soomro T, Haws RA, Darmstadt GL, Bhutta ZA. Reducing stillbirths: prevention and management of medical disorders and infections during pregnancy. BMC Pregnancy and Childbirth 2009; 9 (Suppl 1): S4.*

In this systematic review, the authors looked for evidence about sixteen antenatal interventions with the potential to prevent stillbirths. Of the 345 articles reviewed in this systematic review, clinical trials about syphilis screening and treatment interventions included one Cochrane review and eight interventional, quasi-experimental, or observational studies. The authors found that few studies looked at any of the interventions of interest; the Cochrane review found no eligible studies. In one clinical study, a dose-response protective relationship was found between penicillin treatment and pregnancy outcome. Compared with outcomes of those receiving no doses, one dose of penicillin reduced the risk by 41%; two doses reduced the risk by 65%; and three doses reduced the risk by 79% ($p < 0.0001$). In another clinical study, findings less strongly supported a dose-response relationship, but did suggest that HIV-infected mothers may not benefit from only one dose of penicillin as they do from two or three doses. The authors commented that the need for accurate and timely laboratory testing was a key limiting step for effective interventions.

**Summary of Evidence for USPSTF Recommendation**

In 2004, the USPSTF recommended screening for syphilis for persons at increased risk of syphilis, and for all pregnant women. The USPSTF recommendation statement included as persons at increased risk of syphilis those members of behavioral groups with increased incident rates of syphilis, including: men who have sex with men and engage in high-risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, and those in adult correctional facilities. There is no evidence to support an optimal screening frequency in this population.

Rating: 'A' Recommendation

Rationale: According to the 2004 recommendation statement, (USPSTF 2004) the USPSTF summarized the evidence for this recommendation as follows:

- "Although the USPSTF found no new direct evidence that screening for syphilis infection leads to improved health outcomes in persons at increased risk …there is adequate evidence that screening tests can accurately detect syphilis infection and that antibiotics can cure syphilis. Screening may result in potential harms (such as clinical evaluation of false-positive results, unnecessary anxiety to the patient, and harms of antibiotic use). The USPSTF concludes that the benefits of screening persons at increased risk for syphilis infection substantially outweigh the potential harms (USPSTF 2004)."
- "The USPSTF found observational evidence that the universal screening of pregnant women decreases the proportion of infants with clinical manifestations of syphilis infection and those with positive serologies. The USPSTF concludes that the benefits of screening all pregnant women for syphilis infection substantially outweigh potential harms (USPSTF 2004)."

In its 2004 recommendation statement, USPSTF suggested that screening testing for syphilis be done in two phases: a non-treponemal test (such as the rapid plasma reagin (RPR) test or the Venereal Disease Research Laboratory (VDRL) test) followed by a treponemal test (such as the fluorescent treponemal antigen – absorbed (FTA-ABS) test or the *T. pallidum* particle agglutination (TP-PA) test). Using estimates, the Task Force projected the relative performance of these tests in the general population and in high-prevalence subgroups as follows:

> "Sensitivity of the RPR and VDRL tests are estimated to be 78% to 86% for detecting primary syphilis infection, 100% for detecting secondary syphilis infection, and 95% to 98% for detecting latent syphilis infection. Specificity ranges from 85% to 99% and may be reduced in individuals who have preexisting conditions (i.e., collagen vascular disease, pregnancy, intravenous drug use, advanced malignancy, tuberculosis, malaria, and viral and rickettsial diseases) that produce false-positive results. The FTA-ABS test has a sensitivity of 84% for detecting primary syphilis infection and almost 100% sensitivity for detecting syphilis infection in other stages, and a specificity of 96%. … The yield of screening using a two-step process (RPR followed by confirmatory FTA-ABS) can be estimated using test characteristics and the incidence of syphilis infection in a given population. For example, in the general population (assuming a prevalence of 5 per 100,000, an RPR sensitivity of 91% and specificity of 95%, and FTA-ABS sensitivity of 92% and specificity of 96%), one would have to screen more than 24,000 patients to detect a single case of syphilis infection (number needed to screen [NNS] = 24,000); 200 per 100,000 people screened would have false positive test results. On the other hand, in a high risk population of incarcerated women (assuming a prevalence of 12%, an RPR sensitivity of 91% and specificity of 95%, and FTA-ABS sensitivity of 92% and specificity of 96%), one would have to screen 10 patients to detect 1 case of syphilis infection (NNS = 10); almost 2,000 per 100,000 people screened would have false-negative test results (USPSTF 2004)."

USPSTF considered potential harms consequent to syphilis screening, although acknowledging the relative lack of clinical studies in this area:

"Potential harms of screening may include opportunity costs to the clinician and patient (time, resources, etc.) and false-positive results which may lead to stress, labeling, and further workup. Harms of treatment include adverse drug-related effects including anaphylaxis from penicillin allergy and the Jarisch-Herxheimer reaction (febrile reaction with headache, myalgia, and other symptoms) that may occur within the first 24 hours after any therapy for syphilis (USPSTF 2004)."

In 2009, without modifying the recommendations for syphilis screening of persons at increased risk, the USPSTF reinforced and modified the 2004 recommendation about screening pregnant women (USPSTF 2009), noting that a focused and updated review (Wolff et al. 2009) found articles on the benefit and harm of syphilis screening of pregnant women which reemphasized the importance of the 2004 recommendation. One large study (Cheng et al. 2007) described a three-year screening program for syphilis among more than 400,000 pregnant women in China (2003-2005), in which 94% of eligible women were screened and 95% received treatment. These investigators found decreased syphilis incidence among program participants (from 54 cases per 100,000 women to 22 cases per 100, 000 women), as well as decreased congenital syphilis rates in their infants. Others studies focused on harms from screening and treatment of pregnant women, which Wolff et al. concluded "… a slight risk from harm due to false-positive results and a rare risk for serious allergic reactions to penicillin (Wolff et al. 2009)."

In the 2009 reaffirmation statement, USPSTF emphasized that, for pregnant women:

- "Untreated syphilis during pregnancy is associated with stillbirth, neonatal death, bone deformities, and neurologic impairment.
- "The USPSTF found convincing observational evidence that the universal screening of pregnant women decreases the proportion of infants with clinical manifestations of syphilis infection.
- "All pregnant women should be tested at their first prenatal visit. For women in high-risk groups, many organizations recommend repeat serologic testing in the third trimester and at delivery."

and concluded, "… with high certainty, that the net benefit of screening is substantial for pregnant women." (USPSTF 2009)

The clinical considerations supporting the recommendation identify populations at increased risk for syphilis infection as including men who have sex with men and engage in high risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities, and those with a history of an STD (USPSTF 2009).

**3.b Internal TA**

*Jena AB, Goldman DP, Kamdar A, Lakdawalla DN, Lu U. STDs among users of ED drugs: analysis of claims data. Ann Intern Med. 2010; 153: 1-7.*

In this retrospective review of administrative records representing more than 1,400,000 men aged 40 years or older, the authors found 33,968 men with at least one filled prescription for an erectile dysfunction (ED) medication ('ED users'). The claims information was assembled from a database of pharmacy and medical claims from 44 large US employers during the period from 1997-2006. The incident STI rate during the prior year was compared to ED status. Claims for sildenafil, vardenafil, and tadalafil were included in the analysis. Results showed that the average age for ED users was 61.1 years, compared to an average age of 59.3 years among non-ED users. The association of ED use and incident STIs was significant for all STIs in combination, and individually by STI for chlamydia and for HIV, each at $p < 0.001$. Although not statistically significant, the rate of syphilis in the previous year was higher (14.7/100,000) among ED users, compared to (7.3/100,000) in non-ED users. The authors concluded that older men, and particularly those who use ED medications, may represent a group at increased risk of STIs, and suggested that ED medication use by middle-aged or older men might be a simple screening tool to identify those who may benefit from reminders about safe sexual practices.

*Reece M, Herbenick D, Schick V, Sanders S, Dodge B, Fortenberry JD. Barrier protection use rates in a national probability sample of males and females ages 14 to 94 in the US. J Sex Med. 2010; 7 (Suppl 5): 266-76.*

In this prospective survey, a national probability sample was used to survey 5,865 US male and female adolescents and adults on rates of barrier protection use among sexually active persons. The authors found that the lowest percentages of barrier protection use during the most recent ten vaginal intercourse events were among those of 70 years of age or older, both for men (5.4%, CI 1.7 – 13.4%) and women (1.9%, CI (-0.9) - 12.8%). The authors concluded that this might reflect the increased attention to education about barrier precautions among younger persons who are sexually active.

*Smith KP, Christakis NA. Association between widowhood and risk of diagnosis with STI in older adults. Am J Publ Health. 2009 Nov; 99(11): 2055-62.*

In this prospective survey of a random sample of married Medicare-eligible couples based on Medicare claims data, the authors assessed whether widowhood is associated with STI diagnosis, and whether this association changed after the introduction of sildenafil, an ED prescription medication. The authors analyzed the time to first STI diagnosis in a random sample of married, Medicare-eligible couples, aged 67-99 years, in 1993. Results showed that 21% of male and 43% of female participants lost a spouse during the 9-year study period. Of the male and female participants, 0.65% and 0.97%, respectively, were diagnosed with an STI during this time. Syphilis was diagnosed in 343/2256 male participants, and in 353/4076 female participants. Widowhood was significantly associated with an increased risk of STI for men [HR 1.20 (CI 1.07, 1.34)] but not for women [HR 1.04 (CI 0.96, 1.12)] with the largest effects found 0.5 to 1 year after a wife's death. Also, effects for men were larger after the introduction of sildenafil [HR (post sildenafil) 1.18 (CI 1.02, 1.38)]. The authors concluded that factors for acquiring STIs in older Medicare beneficiaries must include the loss of a spouse, as well as access to ED medications. The authors acknowledged that, among the weaknesses of this claims-based observational study, no conclusions about cause and effect would be warranted, and suggested further study would be appropriate.

*Cheng JQ, Zhou H, Hong FC, Zhang D, Zhang YJ, Pan P, Cai YM. Syphilis screening and intervention in 500,000 pregnant women in Shenzen, the People's Republic of China. Sex Transm Infect 2007; 83: 347-50.*

This retrospective cohort study reviewed the results of a large regional program of free syphilis screening, initiated in response to an increase in congenital syphilis cases. Sera from participating pregnant women were tested with non-treponemal and then with treponemal tests for syphilis. Women with positive test results for syphilis infection were treated and followed up for two years. Infants born to women treated for syphilis were screened for congenital syphilis at birth. The authors found that among 418,871 women screened during three years of the program, 2019 were positive for syphilis, and 91.9% opted for treatment. Of those who screened positive for syphilis 296 (14.7%) showed adverse pregnancy outcomes, including miscarriage, stillbirth, and ectopic pregnancy. Two hundred and seventy-four chose to terminate their pregnancies, and 47 women were lost to followup. Among the remaining 1402 women who continued their pregnancies, 1112 had normal childbirth. Of these, 92 infants were confirmed to be infected with syphilis congenitally. Seventy-six of these 92 cases were born to women who missed out on the screening program, or who were delivered at home and diagnosed later. The success rate for preventing congenital syphilis among children of women participating in this screening and treatment program was 99.1%. The authors acknowledged that failure of follow-up was a major problem, perhaps due to pregnant women returning to their home towns, and suggested that a point-of-care screening test with immediate treatment might reduce the number of congenital syphilis cases. The authors concluded that the program showed some success in preventing congenital syphilis in program participants and made suggestions for program improvements.

**Test Performance**

*Owusu-Edusei K, Koski KA, Ballard RC. The tale of two serologic tests to screen for syphilis—treponemal and nontreponemal: does the order matter? Sex Trans Dis 2010 Dec; 37 (12): 1-9.*

This non-clinical study used models of syphilis screening and treatment to project cost-effectiveness of several alternative approaches, including the usual and 'reversed' testing methods for syphilis screening. The authors used models of four test sequences: non-treponemal test only; treponemal test only; non-treponemal test first (the sequence recommended by CDC); and treponemal test first ('reversed' testing). They then used parameters typical of the United States (as a low incidence region) and compared them with parameters typical of sub-Saharan Africa (as a high incidence region). They modeled costs of a screening program for each region, and costs per case treated. The authors concluded that the non-treponemal test only approach yielded the lowest cost per case treated and relatively few cases of congenital syphilis, neonatal death and stillbirth, compared with no program. The relative effectiveness of the treponemal test first and non-treponemal test first approaches was similar.

*Geusau A, Kittler H, Hein U, Dangl-Erlach E, Stingl G, Tschachler E. Biological false positive tests comprise a high proportion of VDRL reactions in an analysis of 300,000 sera. Int J STD AIDS. 2005; 16: 722-6.*

In this retrospective cohort study, conducted during the years 1988 through 1999 at several hospitals in Vienna, Austria, the authors tested sera using the VDRL and TPHA tests run in parallel. Sera from 301,032 patients were retained for analysis. The male:female ratio of the patients was about 2:3. Of approximately 40,000 patients greater than 60 years of age, biological false positive (BFP) results were seen in about 0.28 – 0.35 % of females' sera, and 0.15 – 0.28 % of males'. The proportion of BFP results was inversely related to the VDRL titer for all serum samples, with the highest proportion of BFPs occurred in sera with VDRL titers of 1:4. Positive results were noted for the TPHA test in 2.5 – 3.5% of patients over the age of 60 years. The authors concluded that any syphilis screening results showing a low-titer positive in older persons should suggest that a BFP might be involved. Because of the relative likelihood of BFPs in low-prevalence populations (such as older persons), the authors questioned the usefulness of non-treponemal tests for syphilis screening.

***Hepatitis B***

A search of relevant published articles was conducted by CMS staff in March and April 2011, using the search terms "hepatitis B", "HBsAg", and "screening", limited to clinical studies published within the last ten years about the effects of hepatitis B screening interventions on behavioral and/or health outcomes. In addition, articles cited in bibliography of any relevant USPSTF recommendation statement(s) were sought. Sixty-eight citations were found and reviewed at the abstract level. Numerous studies in which HBV screening during pregnancy was an outcome, rather than an intervention, were judged not relevant to this topic. Three systematic reviews (Lin 2009, Weinbaum 2008, Wilt 2008) are summarized under the External TA section below (VII.F.2.c). A guideline (Haber 2009) suggesting the burden of cost for managing CHB in children is summarized below under the Internal TA section (VII.F.3.c). In addition, a systematic review (Lee 2006) and two RCTs (Schalm 1989, Stevens 1987) were judged relevant to this topic and are also summarized below. In each section below, articles are listed in reverse chronological order, and then alphabetically by first author.

**1.c Questions**

- Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit is recommended with a grade of A or B by the USPSTF?
- Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit is reasonable and necessary in the prevention or early detection of illness or disability?
- Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit is appropriate for Medicare beneficiaries?

**2.c External TA**

*Lin K, Vickery J. Screening for hepatitis B virus infection in pregnant women: evidence for the U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med. 2009 Jun 16; 150(12): 874-6.*

In this evidence update report for the USPSTF 2009 Recommendation Reaffirmation Statement for screening of pregnant women for HBsAg, the authors searched for large, high-quality studies related to hepatitis B screening in pregnancy that have been published since the 2004 USPSTF recommendation. Eligible studies were limited to English-language systematic reviews, meta-analyses, and randomized controlled trials relating to screening benefits or to newborn immunoprophylaxis to prevent hepatitis B viral infection, published between 2001 and 2008 as well as case series, cohort studies, and other clinical studies in that time period relating to harms of screening. The authors found that no new studies met inclusion criteria. A 2006 systematic review of randomized, controlled trials found that newborn prophylaxis reduced perinatal transmission of HBV infection (Lee et al. 2006, summarized below). All relevant trials were published in 1996 or earlier. The authors concluded that no clinical studies of benefits or harms of HBsAg screening of pregnant women were found in the English-language medical literature.

*Weinbaum CM, Mast EE, Ward JW. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. Hepatology. 2009 May; 49(5 Suppl): S35-S44.*

In this review article, research on the epidemiology and management of hepatitis B in adults was reviewed. The use of testing for hepatitis B markers (such as HBsAg) has been recommended to enable appropriate treatment for infants born to HBsAg-positive mothers and persons infected with human immunodeficiency virus. With the increasing availability of efficacious hepatitis B treatment and better markers for early detection of HCC, CDC in 2008 published new recommendations for expanded screening for CHB in adults, and for management of chronically infected persons and their contacts. The authors reviewed estimates that the cost of HBsAg screening in asymptomatic adults would cost $ 750 – 3750 for each CHB case identified. The authors concluded that:

- The lack of sufficient resources for identification and management of infected persons can be a barrier to implementation of screening programs.
- All persons with HBV infection, including those who lack insurance and resources, will need ongoing medical management and some will need therapy.
- Patient and provider education, developing partnerships between health departments and community organizations, and other resources will be needed to assure appropriate populations are tested and care provided for persons newly identified as HBsAg-positive.

*Wilt TJ, Shamliyan T, Shaukat A, Taylor BC, MacDonald R, Yuan J-M, Johnson JR, Tacklind J, Rutks I, Kane RL. Management of Chronic Hepatitis B. Evidence Report/Technology Assessment No. 174. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) AHRQ Publication No. 09-E002. Rockville, MD. Agency for Healthcare Research and Quality. October 2008.*

This systematic review of evidence was prepared for a National Institutes of Health (NIH) Consensus Conference about CHB management in adults. The authors included original observational studies to assess natural history and randomized controlled trials (RCTs) of adults with CHB published in English to assess treatment effects and harms if they reported mortality, incidence of hepatocellular carcinoma (HCC), cirrhosis or failure, HBeAg or HBsAg, viral load (HBV DNA), alanine aminotransferase (ALT) levels, histological necroinflammatory and fibrosis scores, and adverse events after interferon alfa-2b, pegylated interferon alfa 2-a, lamivudine, adefovir, entecavir, tenovir or telbivudine. The authors calculated relative risk or absolute risk differences at end of treatment and post-treatment. Drugs did not reduce death, liver failure, or HCC in 16 RCTs not designed to test long-term clinical outcomes. However, some studies indicated at least short term effects on certain intermediate outcomes. Evidence from 93 publications of 60 RCTs suggested drug effects on viral load or replication, liver enzymes, and histology at end of treatment and lasting from < 3 to > 6 months off treatment. No one treatment improved all outcomes and there was limited evidence on comparative effects. For example, lamivudine combined with interferon alfa-2b versus lamivudine improved off treatment HBV DNA clearance and HBeAg seroconversion and reduced HBV DNA mutations. Adefovir and pegylated interferon alfa 2-a with lamivudine improved off treatment viral clearance in HBeAg negative patients. There was insufficient evidence to determine if biochemical, viral, or histological measures are valid surrogates of treatment effect on mortality, liver failure, or cancer. The authors concluded that in adults with single or combination drug therapy improves selected virological, biochemical, and histological markers, although no consistent effects were found on all examined outcomes. Evidence was insufficient to assess treatment effect on clinical outcomes, predict individualized patient response, or determine if intermediate measures are reliable surrogates. The authors suggested that future research should assess long-term drug effects on clinical outcomes and among patient subpopulations.

**Summary of Evidence for USPSTF Recommendation**

In 2004, the USPSTF recommended screening for HBV for all pregnant women at the first prenatal visit. The recommendation does not limit such screening either to individuals in identified high-risk groups, or to individuals at increased risk due to residence location (as determined by prevalence rates).

Rating: 'A' Recommendation

Rationale: According to the most recent evidence summary (Lin 2009) the USPSTF was convinced that the major benefit of prenatal HBsAg screening was in reduced transmission rates of HBV infection to the newborn. No studies suggesting either benefit or substantial harm to the mother of HBsAg screening were found in this systematic review of published evidence since 2004. Studies cited by USPSTF showed hepatitis B immunoprophylaxis of infants born to HBsAg positive mothers resulted in decreasing rates of perinatal HBV transmission by as much as 97% (Lee et al. 2006). USPSTF considered potential harms of prenatal HBsAg screening, including those due to overtreatment based on a false-positive result; psychological harms; increased costs; and inconvenience of subsequent testing. It was also noted that, in 2005, as many as 6% of newborn candidates for hepatitis B immunoprophylaxis did not receive the recommended service due to problems with medical records posting laboratory results, and other problems. The USPSTF concluded in their 2009 recommendations (USPSTF 2009) that:

"An estimated 24 000 infants are born each year to women in the United States who are infected with HBV. Between 30% and 40% of all chronic HBV infections result from perinatal transmission. Chronic HBV infections increase long-term morbidity and mortality by predisposing infected persons to cirrhosis of the liver and liver cancer. … "The principal screening test for detecting maternal HBV infection is the serologic identification of hepatitis B surface antigen (HBsAg). Immunoassays for detecting HBsAg have a reported sensitivity and specificity greater than 98%. …

"The USPSTF found convincing evidence that universal prenatal screening for HBV infection substantially reduces perinatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and providing postexposure prophylaxis with hepatitis B immune globulin administered at birth to infants of mothers infected with HBV substantially reduces the risk for acquiring HBV infection.

"The USPSTF found no published studies that describe harms of screening for HBV infection in pregnant women. The USPSTF concluded that the potential harms of screening are no greater than small. …

"The USPSTF concludes that there is high certainty that the net benefit of screening pregnant women for HBV infection is substantial."

The timing of screening was recommended as, "Order HBsAG testing at the first prenatal visit. Re-screen women with unknown HBsAg status or new or continuing risk factors at admission to hospital, birth center, or other delivery setting." Examples of risk factors were injection drug use or treatment of sexually transmitted disease.

**3.c Internal TA**

*Haber BA, Block JM, Jonas MM, Karpen SJ, London WT, McMahon BJ, et al. Recommendations for Screening, Monitoring, and Referral of Pediatric Chronic Hepatitis B. Pediatrics 2009; 124: e1007–e1013.*

This review of an expert consensus meeting about management of hepatitis B in children was published to provide guidance for family practitioners on this infrequent clinical problem. Children with CHB (persistent hepatitis B surface antigen–positive for ≥ six months) are rarely symptomatic and do not generally require treatment. However, they are at increased risk for severe complications later in life, including advanced liver disease and liver cancer. A panel of nationally recognized North American pediatric liver specialists recommended an approach for the screening, monitoring, initial management, and referral of children with CHB. The panel developed recommendations to provide guidance to practitioners on determining what additional tests to conduct, how often to monitor on the basis of test results, and when to refer to a pediatric liver specialist to build a partnership between the practitioner and liver specialist to enhance the success of management of children with this lifelong infection.

*Schalm SW, Mazel JA, de Gast GC, Heijtink RA, Botman MJ, Bänffer JR, Cerards LJ, Zwijnenberg J, Fetter WP, Nuijten SM, et al. Prevention of hepatitis B infection in newborns through mass screening and delayed vaccination of all infants of mothers with hepatitis B surface antigen. Pediatrics 1989, Jun;83(6):1041-8.*

This large prospective randomized clinical study included prenatal HBsAg screening of all pregnant women in three large city hospitals and one rural hospital, as well as hepatitis B immunoprophylaxis of newborns of HBsAg-positive mothers. On a random basis, infants were assigned to either a group receiving recombinant hepatitis B vaccine doses at 0, 1, 2, and 11 months of age (group A), or a group receiving vaccine at 3, 4, 5, and 11 months, with a second dose of hepatitis B immune globulin at 3 months (group B). Results showed that over the two years of the study, 28,412 women were screened for HBsAg. The prevalence was 0.8%. Of the infants of 180 HBsAg mothers, 90 were block-randomized in groups of six (i.e., three infants assigned to group A, then three infants assigned to group B). The authors concluded that mass screening and prophylaxis according to the schedule used in group B will prevent 92% or 331 cases of neonatal HBV infections. The total cost of preventing one case of perinatal HBV infection was estimated to be about $3,000 US.

*Stevens CE, Taylor PE, Tong MJ, Toy PT, Vyas GN, Nair PV, Weissman JY, Krugman S. Yeast-recombinant hepatitis B vaccine. Efficacy with hepatitis B immune globulin in prevention of perinatal hepatitis B virus transmission. JAMA. 1987 May 15;257(19):2612-6.*

This clinical study, in which participants were randomized to different HBV vaccination schedule, focused on the evaluation of recombinant HBsAg vaccine for hepatitis B immunoprophylaxis as employed in an Asian-American immigrant population of 122 mothers and infants on whom at least nine months' followup information was available. Eligibility for the study included continued maternal HBsAg and hepatitis B virus e antigen (HBeAg) positivity through delivery and infants weighing at least 2000 grams with five-minute Apgar scores of seven or more. Recombinant vaccine for hepatitis B and hepatitis B immune globulin were given according to CDC recommendations at that time, with a second vaccine dose at 1 month, and the third dose at six months. Samples of venous blood at birth, and at one, three, six, 12, and 18 months, and a sample of cord blood were taken from each infant. Results demonstrated no difference in the outcome of prophylaxis in the recombinant vaccine group compared to the plasma-derived vaccine. One infant who received the recombinant vaccine died at seven days of age of an inoperable congenital cardiac malformation. No significant adverse events were attributed to the hepatitis B immune globulin or to the vaccine. Minor reactions include local pain and transient mild rashes at injection sites. The authors concluded that combined use of HBIG and recombinant HBV vaccine could prevent hepatitis B in infants born to HBsAg and HBeAg positive women.

***HIBC for the prevention of STIs***

A search of relevant published articles was conducted by CMS staff in March and April 2011, using the search terms "behavioral counseling", "STI prevention", and "STI reduction", limited to studies published within the last ten years about the effects of HIBC on STI-related behavioral and/or health outcomes. In addition, articles cited in bibliography of any relevant USPSTF recommendation statement(s) were sought. Twenty-three citations were found and reviewed at the abstract level. Numerous studies in which HIBC was an outcome, rather than an intervention, were judged not relevant to this topic. Four systematic reviews (Johnson BT 2011, Johnson BT 2009, Johnson WD 2008, and Weinhardt 1999), as well as a fifth (Lin 2008) cited by the USPSTF Recommendation Statement for HIBC for STI risk reduction (USPSTF 2008) are summarized under the External TA or USPSTF Recommendation Evidence sections below (VII.F.2.d). In addition, two RCTs (Carey 2010, Semaan 2010) were judged relevant to this topic and are summarized below under the Internal TA section (VII.F.3.d). In each section below, articles are listed in reverse chronological order, and then alphabetically by first author.

**1.d Questions**

- Is the evidence sufficient to determine that HIBC to prevent sexually transmitted infections for all sexually active adolescents and for adults at increased risk for STIs is recommended with a grade of A or B by the USPSTF?

- Is the evidence sufficient to determine that HIBC to prevent sexually transmitted infections for all sexually active adolescents and for adults at increased risk for STIs is reasonable and necessary in the prevention or early detection of illness or disability?
- Is the evidence sufficient to determine that HIBC to prevent sexually transmitted infections for all sexually active adolescents and for adults at increased risk for STIs is appropriate for Medicare beneficiaries?

**2.d External TA**

The Lin et al. 2008 article which accompanied the USPSTF 2008 recommendation is summarized in the following section. Several other meta-analyses were found dealing with behavioral interventions to reduce risk of sexual HIV transmission: one (Johnson et al. 2011) in adolescents; one systematic review (Weinhardt et al. 1999); and a Cochrane review (Johnson et al. 2008) of behavioral interventions to reduce risk for sexual transmission of HIV among MSM was also noted. A focused meta-analysis of interventions with a majority of African-American participants (Johnson et al. 2009) was also believed relevant as it addressed such interventions for a population group with known disparity in STIs prevalence.

*Johnson BT, Scott-Sheldon LAJ, Huedo-Medina TB, Carey MP. Interventions to reduce sexual risk for HIV in adolescents: a meta-analysis of trials, 1985-2008. Arch Pediatr Adolesc Med. 2011 Jan; 165(1): 77-84.*

These authors conducted a systematic review of the literature on behavioral interventions to reduce sexual risk of HIV among adolescents. Articles published in the medical literature until December 2008 were eligible for inclusion if they: a) evaluated an educational, psychosocial, or behavioral intervention advocating sexual risk reduction and using interpersonal contact; b) used a randomized controlled trial or quasi-experimental design with rigorous controls; c) had behavioral measures of outcome related to sexual risk (e.g., barrier protection use, number of sexual partners); d) focused on adolescents ('pre-university'); and e) included sufficient information to calculate effect size. Some interventions (such as studies of pamphlet impact, 'abstinence' studies, or studies predating the HIV epidemic) were excluded. The authors found that of the 67 studies eligible for analysis, most were US studies conducted in medium to large cities and recruited participants from school or community contexts. A total of 51,240 adolescents were studied with mean age of 15 years. Most (56%) participants were already sexually active. Thirty percent of participants used illegal drugs; 33% drank alcohol. Forty-five percent of participants were African-American. In these studies, the average retention rate of participants was 79% over the study period. Interventions included HIV/AIDS education (91%), active interpersonal skills training (69%), self-management skills training (38%), barrier protection information or demonstrations (38%), and motivational content (12%). Comparisons were often to waiting list / no treatment control (51%) or sometimes to a standard HIV education intervention (29%). The median time at which assessments were conducted was 13 weeks after the intervention (range 0-156 weeks). The authors concluded that relative to comparison conditions, interventions significantly enhanced nine of 10 examined outcomes; however study outcomes varied widely. The authors noted that interventions were more effective when (1) they provided a greater amount of barrier protection skills training or (2) motivational training in each session, and 3) the intervention group reduced frequencies for sexual encounters relative to the control group. The authors commented that effect sizes tended to be larger when the sample of adolescents was from an institutionalized population (such as detainees), when the intervention had more sessions, and when the intervention did not emphasize abstinence. They also commended the trend for improved evidentiary quality in more recent studies

*Johnson BT, Scott-Sheldon LAJ, Smoak ND, LaCroix JM, Anderson JR, Carey MP. Behavioral interventions for African Americans to reduce sexual risk of HIV: a meta-analysis of randomized controlled trials. J Acquir Immune Defic Syndr. 2009 Aug 1; 51(4): 492–501.*

The authors conducted a systematic review of articles about behavioral interventions to reduce HIV including a majority of African-Americans participants. They found 78 randomized controlled trials that sampled at least 50% African-Americans (N = 48,585, 81% African-American), measured barrier protection use or number of sexual partners, and provided sufficient information to calculate effect sizes. Independent raters coded participant characteristics, design and methodological features, and intervention content. The authors found that compared to controls, participants who received a HIV risk reduction intervention improved barrier protection use at short-, intermediate-, and long-term assessments; change was better among MSM and people already infected with HIV, and when interventions provided intensive content across multiple sessions. Intervention participants reduced their number of sexual partners in interventions with intensive interpersonal skills training and in younger samples, especially at delayed intervals. The authors concluded that sexual risk reduction behavioral interventions for African-Americans increased barrier protection use with reduction in number of sexual partners. Translating these interventions and further enhancing them continue as a high priority.

*Johnson WD, Diaz RM, Flanders WD, Goodman M, Hill AN, et al. Behavioral interventions to reduce risk for sexual transmission of HIV among MSM. The Cochrane Collaboration, 2008. J Wiley & Sons, Ltd.*

This systematic review was focused on several objectives: to locate and describe outcome studies evaluating the effects of behavioral HIV prevention interventions for MSM; to summarize their effectiveness; to identify study characteristics associated with effectiveness; and to identify gaps in evidence for future research and policy formation. The authors searched both published and unpublished reports from 1988 through 2007. Studies were considered for inclusion if they examined the effects of behavioral interventions at reducing risk for HIV or STD transmission among MSM. Forty-four studies were found, in which 58 interventions were evaluated based on 18,585 participants. Formats included 26 small group interventions, 21 individual-level interventions, and 11 community-level interventions. Sixteen of 58 studies focused on HIV-positive persons. In 40 interventions, there were reduced occasions of or partners for unprotected high-risk sex practices by 27% (CI: 15% to 37%). The other 18 interventions reduced unprotected high-risk sex practices by 17% compared to standard or other interventions (CI: 5% - 27%). One positive factor noted in multiple studies with favorable outcomes was shorter intervention spans (1 month or less). The authors concluded that behavioral interventions reduce self-reported unprotected high-risk sex practices among MSM.

*Weinhardt LS, Carey MP, Johnson BT, Bickham NL. Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. Am J Public Health. 1999 Sep; 89(9): 1397-405.*

In this systematic review, the authors searched the published literature from 1985 through June 1997 using search terms for AIDS, HIV, test, counseling, outcomes, sex, and related terms, and searched citation lists from retrieved articles. Identified studies were included if they a) specified when participants underwent HIV testing and counseling (HIV-CT), b) measured sexual activity or a proxy outcome (e.g., STI incidence), c) included at least two encounters with participants over time, and d) provided summary or inferential statistics to calculate within-group effect sizes. Twenty-seven studies, representing 19,597 participants, met the inclusion criteria. A few studies mentioned characteristics of the counseling intervention used, which included group discussion, videotaped presentations, and partner counseling. Self-reported outcomes included number of sexual partners, barrier protection use, and unprotected intercourse. Two studies provided STD incidence on participants. Overall, HIV-positive participants and HIV-serodiscordant couples in the 27 studies examined reduced their frequency of unprotected intercourse and increased their barrier protection use, relative to HIV-negative and untested participants, after receiving HIV counseling and testing. Furthermore, in two studies, HIV-positive participants exhibited reduced STD incidence relative to HIV-negative and untested participants. The authors concluded that these findings indicate that HIV-CT is an effective secondary HIV prevention strategy; that is, participants who learned that they were HIV-positive did reduce their sexual risk behavior.

**Summary of Evidence for USPSTF Recommendation**

In 2008, the USPSTF issued a recommendation statement about using HIBC in sexually active adolescents and adults to prevent STIs (USPSTF 2008). The USPSTF concluded that "(t)here is convincing evidence that high-intensity behavioral counseling interventions targeted to sexually active adolescents and adults at increased risk for STIs reduce the incidence of STIs. These results were found 6 and 12 months after counseling took place."

In their recommendation, USPSTF noted that:

"… there is at least moderate certainty that high-intensity behavioral counseling interventions can lead to moderate net benefits for sexually active adolescents and adults who are at increased risk for STIs. … Most of the evidence found by the review concerns high-intensity interventions given to sexually active adolescents and to adults at increased risk for STIs.

"Five of 6 trials demonstrated statistically significant reductions in biologically confirmed STIs at 6 and 12 months after the interventions. The absolute risk reduction rate ranged from 2.6% to 11.1%, with generally higher rates of reduction among adolescents. As noted, the interventions in this group were considered "high-intensity"; they included a single 4-hour session, three 1-hour sessions over 3 consecutive weeks, four 4-hour sessions, and a 10-session intervention.

"One fair-quality study found that HIV testing in combination with two 20-minute individual counseling sessions (a less intensive intervention than the others reviewed) led to a significant reduction in new STIs, including chlamydia, gonorrhea, syphilis, and HIV, at both 6 and 12 months after the intervention.

"Another study found that a single, 20-minute, one-to-one skills counseling session delivered in a primary care office may reduce STIs 12 months thereafter among women who are at increased risk for STIs. Because the reported results combined women who received this low-intensity intervention with a group of women who received 200 minutes of group counseling, additional research is needed to determine whether lower-intensity interventions can be effective."

The USPSTF also indicated that "No evidence of significant behavioral or biological harms resulting from behavioral counseling about risk reduction has been found. Given its findings that potential harms of counseling are no greater than small, "… The USPSTF concluded that there is moderate certainty that high-intensity behavioral counseling has a moderate net benefit for sexually active adolescents and for adults who are at increased risk for STIs. Rating: 'B' "

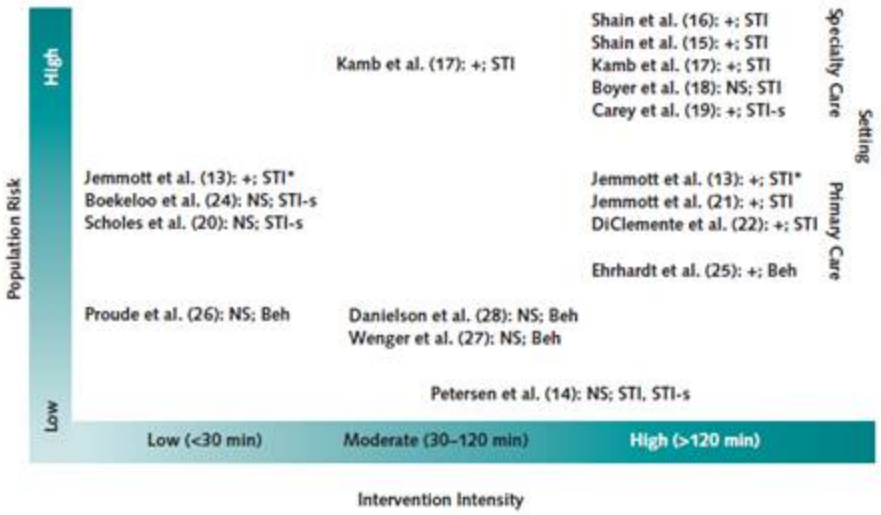
*Lin JS, Whitlock E, O'Connor E, Bauer V. Behavioral counseling to prevent STIs: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2008; 149: 495-506*.

In this systematic review which is directly related to the USPSTF recommendation, the authors found evidence that HIBC is effective in various high-risk populations for prevention of STIs. Reviewers examined 21 articles published through December 2007, which represented 15 fair- or good-quality randomized, controlled trials that evaluated behavioral counseling interventions feasible in primary care and one fair-quality and one good-quality controlled trial with study samples representative of primary care populations in English-speaking countries. Comparative effectiveness trials that did not include a true control group were excluded, as were studies in which the participants were HIV-positive. These authors used the definitions that 'behavioral counseling' was any intervention that included "some provision of education, skills training, and guidance on how to change sexual behavior, delivered alone or in combination with other interventions intended to promote sexual risk reduction or risk avoidance". 'High-intensity' described "multiple-visit interventions requiring more than 2 hours in total".

In this meta-analysis, these authors found evidence of 'modest' reduction in STIs at 12 months among sexually active adolescents and among high-risk adults. They also found improved behaviors that decreased STI risk, including: increased adherence to treatment recommendations for women in STI clinics; improved general contraceptive use in male adolescents; and decreased nonsexual risky behavior and pregnancy in sexually active female adolescents. No evidence of substantial behavioral or biological harms due to risk reduction counseling was found. The authors acknowledged that the heterogeneity of studies' settings, protocols, and target populations were weaknesses of these studies. In addition, the authors suggested that caution be used in interpreting studies relying on self-reported sexual behaviors or STIs. The authors concluded that HIBC was efficacious for reducing STI incidence and in decreasing the frequency of risky sexual behaviors during the 12 months following counseling.

The following pictorial representation of Figure 3 from that meta-analysis shows the intensity of counseling from low to high, and population risk (from low to high) for STD prevalence or risk behavior. A key point illustrated in this diagram (in the dotted rectangle in upper right corner of figure) is the beneficial effect on STI incidence (noted as "+; STI" in the figure) found in seven of nine trials using HIBC as interventions for moderate to high-risk populations.

*Figure 3.* Summary of findings: intervention intensity vs. population risk and setting.




These authors also concluded that additional trial evidence would be needed to assess the impact on STI incidence or risk behaviors both for lower-intensity behavioral counseling interventions and for lower risk patient populations (Lin et al. 2008).

**3.d Internal TA**

*Carey MP, Senn TE, Vanable PA, Coury-Doniger P, Urban MA. Brief and Intensive Behavioral Interventions to Promote Sexual Risk Reduction among STD Clinic Patients: Results from a Randomized Controlled Trial. AIDS Behav. 2010 June; 14(3): 504–17.*

The authors conducted an RCT to evaluate the separate and combined effectiveness of brief and intensive interventions for sexual risk reduction among patients at a STD clinic. There were 1483 participants (54% men; 64% African-American; *M* = 29.2 years old) from a publicly-funded, walk-in STD clinic participated. Patients completed a baseline assessment, and then were randomized to one of six intervention arms; each arm combined a brief intervention with an intensive intervention. The interventions provided different levels of information, motivational counseling, and behavioral skills training, guided by theory, formative research, and empiric precedent. Follow-up assessments, including STD screening, occurred at three, six, and 12 months post-intervention. The authors found that infection rates declined from 18.1% at baseline to 4.5% at 12 months. At a three-month follow-up, patients reported fewer sexual partners, fewer episodes of unprotected sex, and a lower percentage of unprotected sexual events; they strengthened sexual health knowledge, safer sex attitudes and intentions, and self-efficacy beliefs. No consistent pattern of differential risk reduction was observed among the six intervention conditions, nor was any evidence of decay from three to 12 month follow-ups obtained. The authors concluded that implementing behavioral interventions in a STD clinic was associated with significant reduction of sexual risk behavior, and risk antecedents.

*Kamb ML, Fishbein M, Douglas JM, Rhodes F, Rogers J, Bolan G, et al. Project RESPECT study group, 1998: Efficacy of risk-reduction counseling to prevent HIV and STDs: a randomized controlled trial. JAMA 1998; 280: 1161-7.*

In this RCT, the authors investigated the efficacy of counseling to prevent infection with both HIV and with STDs (NG, CT, and syphilis). The participants were 5758 heterosexual HIV-negative patients who presented to a public health STD clinic in five US cities. Participants in the intervention arms of this trial received either enhanced counseling with four interactive, theory-based sessions completed within four weeks of enrollment (Arm 1), brief interactive counseling (two interactive risk-reductive sessions completed within ten days) (Arm 2), or two brief didactic messages (each about five minutes long) which the authors believed to be typical of current care (Arms 3 and 4). Free barrier protection devices were provided to attendees in all arms at each intervention session; a monetary incentive was also given for each interactive counseling session attended after the first, with a greater total monetary incentive to those completing all sessions in Arm 1. Additional monetary incentives were given for returning for followup STD examinations and for completing followup questionnaires. Arms 1, 2, and 3 were actively followed up with questionnaires and STD testing at six and twelve months. Outcome measures were new diagnoses of gonorrhea, chlamydia, syphilis or HIV defined by laboratory tests. The authors found the following results. Among participants, the male: female ratio was four:three. As a percentage of all participants, those attending each STD clinic site ranged from 18% - 24%. Median age of all participants was 25 years. Thirty percent had an STD by lab testing on enrollment, and were treated according to standard guidelines. Sixty-three percent reported a prior STD. Forty-eight percent reported at least one new sex partner in the prior three months. Thirteen percent reported barrier protection use during all intromissive sexual episodes occurring in the prior three months. The rate of completion of counseling interventions was lower for Arm 1 than for Arm 2 (72% vs. 85%, $p < 0.01$), although a majority reported the sessions to be informative, good, and helpful. Followup interviews at three months indicated that those in Arms 1 and 2 who had received enhanced counseling reported 'no unprotected vaginal sex' significantly more often than those who had received only brief didactic messages (RR 1.21, 95% CI 1.09-1.35). At twelve months, enhanced counseling participants (Arm 1) were significantly more likely to report 'no unprotected sex' than participants in other study arms ($p = 0.02$). Results of laboratory testing indicated that, at the 12 month visit, 549 (12.7%) of all participants had a new STD, including 271/549 infected with gonorrhea; 315/549 with chlamydia; and 25/549 with syphilis (some participants had more than one type of STD). Fewer STDs developed among participants who had received either of the interactive interventions (Arms 1 and 2) than in those who had received brief didactic messages (Arms 3 and 4) through the 12-month followup STD examination (RR 0.81; 95% CI: 0.67-0.98). The numbers of participants counseled per STD averted during the twelve month study interval were 21 for the enhanced counseling Arm 1 and 38 for the brief counseling Arm 2. The protective effect of counseling interactions was seen consistently across the five study sites, and was similar for participating males and females. The authors concluded that providing two to four sessions of interactive counseling to prevent STDs was more effective than providing two brief didactic messages in preventing new STDs and in increasing barrier protection use.

*Semaan S, Neumann MS, Hutchins K, D'Anna LH, Kamb ML for the Project RESPECT Study Group. Brief counseling for reducing sexual risk and bacterial STIs among drug users—Results from project RESPECT. Drug Alcohol Depend 2010 Jan 1; 106(1): 7–15.*

This randomized controlled study was performed to assess the efficacy on sexual risk behaviors and on bacterial STIs of a brief risk reduction counseling ('brief' RRC or BRRC) among participants of a larger study (Project RESPECT, a multi-city HIV risk reduction study, and the source of the article discussed above (Kamb 1998)) and to examine BRRC's applicability to current users of heroin, cocaine, speedball, or crack. Participants were randomly assigned to one of three individual, face-to-face interventions (i.e., enhanced, brief, or informational) with varying durations and contents. The enhanced RRC provided four interactive, counseling sessions based on behavioral change theories. The brief RRC received interactive cognitive and action-oriented goal-setting strategies to reduce sexual risk, based on client-centered HIV counseling. The informational arm received didactic messages about HIV and STIs. Participants in all arms received barrier protections and free treatment for bacterial STIs. Baseline demographic and economic variables, risk behaviors, and prevalence and correlates of bacterial STIs for ever-injectors ([EIs], N= 335) and never-injectors ([NIs], N= 3963). Changes in risk behaviors and bacterial STIs for EIs and NIs were evaluated at 12 months. The authors found that at baseline, 19% of EIs and 29% of NIs had bacterial STIs. Both groups had similar baseline STI correlates. At 12 months, 4% of EIs and 7% of NIs had bacterial STIs. Twelve-month cumulative incidence of bacterial STIs in the brief RRC was 21% lower among EIs and 18% lower among NIs compared to the informational condition. At 12 months, EIs reported fewer sexual risk behaviors than at baseline. Baseline positivity rates of trichomoniasis in EIs (female: 15%) and in male and female EIs of HSV-2 (39%, 68%), HBV (41%, 37%), and HCV (60%, 58%) were similar to rates in present-day drug users. The authors concluded BRRC reduced sexual risk and bacterial STIs in EIs. As a note added in proof, the authors indicated that results of prior studies were similar to those of this study, having shown that both the enhanced and brief RRC interventions showed a similar 20% reduction in cumulative, incident, bacterial STIs through 12 months compared with the informational intervention (Kamb et al. 1998).

**Cost-effectiveness of STI Screening and of HIBC for Prevention of STIs**

A number of authors have addressed the question of cost for STI screening and HIBC efforts. Several recent publications are discussed below.

*Pultorak E, Wong W, Rabins C, Mehta SD. Economic Burden of STI: incidence and medical cost of chlamydia, gonorrhea and syphilis among Illionois adolescents and young adults, 2005-2006. Sex Transm Dis 2009 Oct; 36(10: 629-36*

In this retrospective economic analysis, the authors estimated STI costs for chlamydia and gonorrhea based on incident STI data from the Illinois Department of Health and cost data from the literature. They calculated that in the 15-24 year old age group, chlamydia incidence and costs were 5,030 infections / 100,000 per year, and $27,576,686 in 2005, and that gonorrhea incidence and costs were 1,740 infections / 100,000 per year and $7,546,500 in 2005. They concluded that although these estimates might be conservative, they highlighted the economic burden of STI in the community, and the potential impact of STI prevention efforts, especially among those at high risk.

*Bateman DA, Phibbs CS, Joyce T, Heagarty MC. The hospital cost of congenital syphilis. The Journal of Pediatrics 1997 May; 130 (5): 752-8.*

The authors conducted this retrospective case-control study to estimate costs for hospital care of congenital syphilis cases compare with infants without syphilis. The study group included all live-born singleton neonates with birth weight greater than 500 gm at an inner-city municipal hospital in New York City in 1989. The authors also compared the characteristics of 114 infants with CDC case-definition compatible congenital syphilis with those of 2906 infants without syphilis. Cost estimates were based on New York State newborn diagnosis-related groups (DRG) reimbursements adjusted for length of stay, birth weight, preterm delivery, and selected maternal risk factors, including infection with the human immunodeficiency virus, cocaine use during pregnancy, and history of injected drug use. The authors found that for infants with congenital syphilis, the unadjusted mean cost ($11,031) and the median cost ($4,961) were more than three times larger than those for infants without syphilis ($p < 0.01$). After adjustment, congenital syphilis was associated with an additional length of hospitalization of 7 1/2 days and an additional cost of $4,690 (both $p < 0.01$) above mean study population values (7.13 days, $3473). The authors concluded that based on the number of nationally reported cases (1991 to 1994), the average annual national cost of treating infants with congenital syphilis is approximately $18.4 million (1995 dollars).

*Schalm SW, Mazel JA, de Gast GC, Heijtink RA, Botman MJ, Bänffer JR, Cerards LJ, Zwijnenberg J, Fetter WP, Nuijten SM, et al. Prevention of hepatitis B infection in newborns through mass screening and delayed vaccination of all infants of mothers with hepatitis B surface antigen. Pediatrics 1989, Jun;83(6):1041-8.*

In this large prospective randomized clinical study (reviewed above: Section VII.F.3.c) of the effects of prenatal HBsAg screening of all pregnant women, the authors also studied costs of this screening program to prevent cases of perinatal HBV infection. Results showed that over the two years of the study, 28,412 women were screened for HBsAg. The prevalence was 0.8%. The authors concluded that mass screening and immunoprophylaxis was associated with a cost per case prevented was ~ $3,000 US.

**4. Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting.**

CMS did not hold a MEDCAC meeting on these topics.

**5. Evidence-based clinical guidelines**

U.S. Preventive Services Task Force Recommendations for STIs (*see Background Section above*).

CDC Sexually Transmitted Diseases Treatment Guidelines, 2010 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5912a1.htm?s_cid=rr5912a1_w).

The CDC guidelines state the following:
"The prevention and control of STDs are based on the following five major strategies:

- education and counseling of persons at risk on ways to avoid STDs through changes in sexual behaviors and use of recommended prevention services;

- identification of asymptomatically infected persons and of symptomatic persons unlikely to seek diagnostic and treatment services;
- effective diagnosis, treatment, and counseling of infected persons;
- evaluation, treatment, and counseling of sex partners of persons who are infected with an STD; and
- pre-exposure vaccination of persons at risk for vaccine-preventable STDs.

Primary prevention of STDs begins with changing the sexual behaviors that place persons at risk for infection. …As part of the clinical interview, health-care providers should routinely and regularly obtain sexual histories from their patients and address management of risk reduction as indicated in this report (CDC Sexually Transmitted Diseases Treatment Guidelines, 2010)."

The American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG) also provide recommendations on screening for STIs. The following tables provide a comparison of the recommendations from USPSTF, CDC, AAFP and ACOG for the screening of STIs. (the following tables are summarized from Tables 3 and 4 in USPSTF Recommendation for STI Screening document http://www.uspreventiveservicestaskforce.org/uspstf08/methods/stinfections.htm.)

**Comparison of STI Screening Recommendations for Sexually Active Nonpregnant Women**

| STI | USPSTF | CDC | AAFP | ACOG |
|---|---|---|---|---|
| Chlamydia | Screen women younger than 25 years and others at increased risk | Screen women 25 years and younger and others at increased risk | Screen women 25 years and younger and others at increased risk | Screen women 25 years and younger and others at increased risk |
| Gonorrhea | Screen women younger than 25 years and others at increased risk | Screen women at increased risk | Screen women younger than 25 years and others at increased risk | Screen adolescents and others at increased risk |
| | | | | |

| STI | USPSTF | CDC | AAFP | ACOG |
|---|---|---|---|---|
| Syphilis | Screen women at increased risk | Screen women exposed to syphilis | Screen women at increased risk | Screen women at increased risk |
| Hepatitis B | Do not screen general population | Provide prevaccination screening for women at increased risk | Do not screen general population | No specific recommendation |

**Comparison of STI Screening Recommendations for Pregnant Women**

| STI | USPSTF | CDC | AAFP | ACOG[2] |
|---|---|---|---|---|
| Chlamydia | Screen women younger than 25 years and others at increased risk | Screen all | Screen women 25 years and younger and others at increased risk | Screen women at increased risk |
| Gonorrhea | Screen women younger than 25 years and others at increased risk | Screen women at increased risk | Screen women at increased risk | Screen women at increased risk |
| Syphilis | Screen all | Screen all | Screen all | Screen all |
| Hepatitis B | Screen all | Screen all | Screen all | Screen all |

**Guidelines for HIBC for the prevention of STIs**

The USPSTF recommended HIBC for the prevention of STIs for all sexually active adolescents and for adults at increased risk for STIs (USPSTF Recommendation Statement 2009). The CDC supports "…education and counseling of persons at risk on ways to avoid STDs through changes in sexual behaviors and use of recommended prevention services…" as one of its major strategies in the prevention and control of STDs (CDC 2010B). The AAFP and the ACOG, as well as other professional societies, also support counseling /education regarding the risks of STIs.

## 6. Public Comments

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

### Initial Public Comments

CMS received six comments during the initial public comment period. A summary of these comments can be found in the proposed decision memorandum and the complete text of these comments is available on the CMS website at View Public Comments .

### Public Comments on the Proposed Decision Memorandum

CMS received fifteen comments on the proposed decision memorandum. Of the fifteen comments, one was from a pediatrician, one was from a registered nurse, one was from a maternal-child nurse, ten were from interested organizations, and two were from the general public. All of the fifteen comments were generally supportive of our proposed decision to provide coverage for screening for the specified STIs and for HIBC to prevent STIs. However, a number of concerns were expressed about certain aspects of the proposed decision. These concerns are categorized and addressed as follows.

**Extend Coverage Beyond Primary Care**

There were a number of commenters that expressed concerns about the requirements in our decision around primary care practitioners and primary care settings. The commenters have requested that we extend coverage to STI screening and HIBC to non-primary care providers, such as those who specialize in, or possess expertise related to STIs and/or HIV care, licensed clinical social workers, and other health educators. In addition, they feel we should expand coverage to appropriate clinical setting to include:

- HIV clinics
- Family planning clinics
- School-based health centers
- STI or STD clinics
- State, county and local health departments and affiliated specialty clinics
- Ryan White-funded safety-net clinics

It was stated that patients at STD clinics belong to young, minority, and poor populations that are bearing a much higher burden of STD disease and are less likely to have a primary care physician. One commenter felt that women are more likely to have their infections detected in the context of a contraceptive or prenatal visit and for many women family planning clinics are their entry point into the health care system. They stated this is especially true for women with incomes below the poverty level, uninsured, Hispanic and black.

*Response: CMS appreciates the concerns expressed by these commenters. CMS makes national coverage determinations for Medicare beneficiaries. Most Medicare beneficiaries are over 65 years of age however we do have approximately eight million beneficiaries under the age of 65 due to end stage renal disease (ESRD) or a disability. A very small number of the under 65 Medicare population are under the age of 19.*

*While CMS is providing coverage for additional preventive services, we believe it is important that these preventive services should be provided in a coordinated approach as part of a comprehensive prevention plan within the context of the patient's total health care. Primary care practitioners are characterized by their coordination of a patient's comprehensive healthcare needs. Primary care practitioners are generalists who are specifically trained to provide primary care services. Other provider specialties may provide patient care in other settings but do not offer care in the context of being the coordinator of the patient's healthcare needs, not limited by problem origin or diagnosis. Coordination of health services is especially important in the presence of the coexisting health issues of our Medicare beneficiaries.*

*Though primary care physicians may employ the services of other professionals who furnish care under direct supervision, Medicare payment is made to the primary care provider. Changes to the "incident to" provision itself are beyond the scope of this decision and we will not address them. All current CMS requirements apply, including those in the Medicare Benefit Policy Manual for "incident to" services furnished in a physician's office where there is direct physician personal supervision (https://www.cms.gov/manuals/Downloads/bp102c15.pdf*

*As we state in section VII of this decision memorandum, the USPSTF conducts rigorous reviews of the evidence to create evidence-based recommendations for preventive services in the primary care setting. Conceivably, state and local health clinics or family planning clinics, if they are functioning as the primary care provider for a Medicare beneficiary, could be eligible for reimbursement for these services if the care providers are eligible Medicare providers and meet the definition of primary care setting provided in this decision memorandum.*

One commenter stated that while they recognize that the majority of STIs are diagnosed in the private sector and that primary care providers were well situated to address the sexual health needs of many of their clients; they also stated that follow-up and treatment may be problematic for primary care providers with an example that antimicrobials to treat certain STIs are often not available or easily acquired in a primary care setting when the patient needs treatment.

*Response: Antimicrobial treatment is beyond the scope of this decision memorandum. If the primary care practitioner is unable to provide the appropriate treatment for a diagnosed STI, we would expect they would make the appropriate referral to insure the patient received the medically necessary and appropriate care.*

Some of the commenters stated concerns that primary care practitioners did not have the time, resources or skills to conduct these services. It was stated that STI/STD specialists and /or HIV care providers may be better equipped to handle treatment for certain STIs, especially in individuals infected with HIV.

*Response: CMS believes that primary care practitioners are on the front lines of health care in providing prevention services. We agree with the commenter's statement that the majority of STIs are diagnosed in the private sector and that primary care practitioners were well situated to address the sexual health needs of many of their clients. Again, we do not address treatment issues in this decision memorandum. As preventive services gain recognition of their potential to improve the health status of the individual and the community, we believe the primary care provider is in the unique position to provide a comprehensive and coordinated approach that will optimized the benefits of these services.*

One commenter felt that the Medicare decision memo should be aligned with the Affordable Care Act provision interim rule as well as the USPSTF recommendations which they interpret to require coverage of services in settings specified in the USPSTF recommendations and does not have a blanket primary care setting requirement.

*Response: CMS provides coverage for additional preventive services pursuant to §1861(ddd) of the Social Security Act. We are in full compliance with the regulations (§410.64) in providing services for screening for STIs and HIBC to prevent STIs. These regulations are more fully explained in section III of this decision memorandum.*

**Confidentiality Issues**

A number of commenters stated that CMS cannot assume that patients will seek STI services at their primary source of other care. A number of commenters noted concerns about the importance of confidentiality related to these services. Individuals prefer options outside of their primary care providers for STI screening and testing because of the stigmatizing nature of these services. It was stated that coverage of these services should reflect actual patient patterns and preferences for seeking care. A commenter noted that a perceived lack of access to confidential care is a significant barrier to receipt of these health services especially for adolescents. Parental notification and consent and the explanations of benefits were identified as major obstacles to adolescents' access to confidential care. It was recommended that STI screening and HIBC services not be listed on the Medicare Summary Notice sent to beneficiaries in order to prevent the inadvertent disclosure of the receipt of these services to individuals other than the client. It was also stated that clients at STI clinics often possess primary care coverage, but choose public clinics for their STI services because of concerns about confidentiality.

*Response: CMS appreciates the sensitive nature of these services and the importance of confidentiality and we believe that primary care practitioners share this understanding. We note that this decision does not compel any patient to seek care in a covered setting, and that some patients may, for personal reasons, choose to obtain care elsewhere. That choice is beyond the scope of this determination. In reference to comments about the explanation of benefits (EOB), an EOB is sent to the beneficiary for any service provided for which a claim for reimbursement is submitted by the provider.*

*If individuals are seeking testing for STIs, they may more likely have symptoms so this would not be screening. The Medicare adolescent population is very small and part of our ESRD or disabled Medicare population so they may not fit the usual profile of adolescents seeking services at STD clinics.*

**Availability of Counseling Services to Adolescents**

Two commenters suggested that counseling should also be available for adolescents who may soon engage in sexual activity. One commenter urged CMS to determine that adolescents evaluated to be at-risk of initiating sexual activity in the near future be eligible for coverage of HIBC.

*Response: One of the requirements for CMS to provide coverage for additional preventive services is that the service be recommended with a grade A or B by the USPSTF. HIBC to prevent STIs is recommended by the USPSTF for all sexually active adolescents and for adults at increased risk for STIs with a grade B. The USPSTF gave a grade I for behavioral counseling for non-sexually-active adolescents and in adults not at increased risk for STIs. Therefore, non-sexually active adolescents are not covered at this time for this service.*

**HIBC to prevent STIs**

A number of commenters supported our coverage for counseling and two commenters specifically supported the two, 20 to 30 minute, individual, face to face sessions for HIBC.

*Response: CMS appreciates these comments.*

One commenter objected to our limitation of HIBC to two sessions. This commenter felt that this was inconsistent with USPSTF recommendations.

*Response: While the USPSTF described the types of counseling used in the studies they reviewed, they did not specifically endorse any one type of counseling in the recommendation. As we mentioned in the analysis section (section VIII) of our proposed decision memorandum, "The preponderance of the published clinical trials included the adolescent and young adult population. This population is not sufficiently representative of the Medicare population to convince us that the range of frequency of the counseling sessions identified in the available clinical trials are directly generalizable to the core Medicare population." CMS feels we have identified the elements of counseling that would be most beneficial to our population and we believe that a structured HIBC program can be effectively delivered in two individual, 20-30 minute, face to face sessions for the Medicare population.*

**Miscellaneous Issues**

One commenter recommended that we develop distinct codes for the HIBC to make tracking of this benefit more manageable.

*Response: The focus of the decision memorandum is the evidence supporting coverage of this service and does not address coding. Coding instructions are part of the implementation process and this will be communicated in the normal process to our contractors and in a provider education article.*

Two commenters suggested that HIV be added to the list of high/increased risk.

*Response: The determinants of high/increased risk are based on USPSTF guidelines. One of the determinants of high/increased risk is having an STI within the last year. We feel this is already inclusive of HIV and does not require adjustment.*

One commenter requested that we modify the decision to clarify that age and behavior-based risk factors can be considered. Another commenter requested that we add age clarification for screening for non-pregnant women.

*Response: We believe both these factors relevant to the USPSTF recommendations are already identified in the list of determinants for high/increased risk.*

One commenter had a concern that pediatricians are absent from the primary care physician listing in the decision summary.

*Response: Physicians who have a primary specialty designation of pediatric medicine are included in the definition of primary care physician for purposes of this decision memorandum.*

One commenter recommended that we mention the other sexual health related preventive services already covered by Medicare.

*Response: The HIV NCD is mentioned in the background section of the decision memorandum. A list of the Medicare preventive services can be accessed at http://www.medicare.gov/navigation/manage-your-health/preventive-services/preventive-service-overview.aspx?AspxAutoDetectCookieSupport=1.*

One commenter encouraged CMS and CDC to monitor changes in screening rates or case findings as a result of these activities.

*Response: CMS appreciates your comment.*

One commenter recommended that the memo clearly state whether Medicare Part D formularies include the required antibiotics consistent with the 2010 STD Treatment Guideline.

*Response: Part D formularies fall outside the scope of the national coverage analysis.*

A recommendation was made that CMS work with CDC to develop a definition of community risk which indicates to providers when STI screening and HIBC efforts are relevant and needed and would be reimbursable.

*Response: CMS appreciates this comment. The CDC and state and local health departments are excellent sources for information on the incidence and community risks of STIs.*

*The references identified in the public comments are listed in Appendix A.*

**VIII. Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Since January 1, 2009, CMS is authorized to cover "additional preventive services" (see Section III above) if certain statutory requirements are met as provided under §1861(ddd)of the Social Security Act. Our regulations at 42 CFR 410.64 provide:

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.
(2) Recommended with a grade of A or B by the United States Preventive Service Task Force.
(3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

CMS notes that any effect of the use of these screening tests is their coordination with treatment and counseling services. CMS concludes that FDA approval or clearance of screening tests used consistent with FDA approved labeling provides a greater likelihood that a potential harm of screening testing, that is, taking action based on inaccurate screening test results, can be avoided. We further conclude that compliance by testing laboratories with CLIA regulatory requirements provides an additional, on-going safeguard for screening test quality. CMS considers these conditions essential to maximize patient safety.

In addition, CMS acknowledges the USPSTF's statement that its evidence supports use of the primary care setting for clinical preventive care services. USPSTF creates evidence-based recommendations for preventive services that should be provided in the primary care setting (2010 -2011 USPSTF Clinical Preventive Services Guide). The judgments that USPSTF makes about a particular service are based on whether providing these services in primary care will realize the expected level of benefit (2010 -2011 USPSTF Clinical Preventive Services Guide).

***Chlamydia and Gonorrhea***

*Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and or gonorrhea is recommended with a grade of A or B by the USPSTF?*

USPSTF Summary of Recommendation on Screening for chlamydial infection (2007)

- "The U.S. Preventive Services Task Force (USPSTF) recommends screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk. Grade: A Recommendation.
- The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk. Grade: B Recommendation."

USPSTF Summary of Recommendation on Screening for gonorrhea (2005)

- "The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors; go to Clinical Considerations for further discussion of risk factors). Grade: B Recommendation."

*CMS concludes that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea is recommended with a grade of A or B by the USPSTF*.

*Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea provides improved outcomes in the prevention or early detection of illness or disability?*

In combination with the meta-analyses cited by the USPSTF in its recommendations, CMS finds that the systematic reviews and RCTs summarized above represent high-quality sources for evidence which support improved outcomes from screening for CT/NG STIs. We note that an opportunity exists for additional clinical studies in older women, as well as for studies of the effects of CT and/or NG STI screening of men at increased risk.

Based on published meta-analyses, CMS acknowledges that evidence demonstrates that screening for CT/NG STI has been reliably linked to reductions in sexual risk behavior, to reductions in CT/NG incident infections, and to reduced risk of consequences of CT/NG infections (such as PID). The systematic review of Meyers et al. 2007 depends on certain key studies, such as that of Østergaard et al. 2000, as evidence for this effect. Some more recent studies (e.g., Oakeshott et al. 2010) tend to confirm this effect.

*After careful review of the available body of evidence, we conclude that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea provides improved outcomes in the prevention or early detection of illness or disability.*

*Is the evidence sufficient to determine that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea is appropriate for Medicare beneficiaries?*

We note that CT / NG screening appropriately addresses a need of sexually active persons enrolled in Part B of the Medicare program, including adolescents who are sexually active, women of child-bearing ages and sexually active older individuals of both genders. Individuals eligible to enroll in Medicare Part B would potentially include both younger beneficiaries, such as those covered due to a qualifying disabling condition or those with end-stage renal disease, in addition to older beneficiaries. While acknowledging that these subgroups represent a relatively minor fraction of all beneficiaries of the Medicare program, Lindau 2007 informs that older individuals remain sexually active even into the eighth and ninth decades of life (Lindau et al. 2007). CDC surveillance information shows the risk of STIs is present in younger individuals as well as the over 65 population (CDC Summary of Notifiable Diseases 2008, Table 3, p. 32 (published 2010)).

Given that risk of CT / NG STIs has no upper age limit, CMS concludes that the benefits of screening for STIs (diagnosing an existing infection, allowing for the treatment of the infection, and providing HIBC for the prevention of STIs) are generalizable to the older as well as the younger Medicare population.

*After careful review of the available body of evidence, we conclude that screening all sexually active women, 24 years of age or younger (pregnant or nonpregnant), and all older women (pregnant or nonpregnant) at increased risk for chlamydia and/or gonorrhea is appropriate for Medicare beneficiaries.*

***Syphilis***

*Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is recommended with a grade of A or B by the USPSTF?*

USPSTF Summary of Recommendations for syphilis infection(2009)

- "The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen persons at increased risk for syphilis infection. Grade: A Recommendation.
- The USPSTF strongly recommends that clinicians screen all pregnant women for syphilis infection. Grade: A Recommendation."

*CMS concludes that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is recommended with a grade of A or B by USPSTF.*

*Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis provides improved outcomes in the prevention or early detection of illness or disability?*

CMS acknowledges the demonstrated efficacy of syphilis screening and treatment in preventing fetal loss, neonatal illness, and maternal sequelae of syphilis. This effect of antenatal syphilis screening is supported by the studies described in Cheng et al. 2007 and Menezes et al. 2009, in both of which prenatal syphilis screening is associated not only with the benefit of disease treatment, but also with decreased fetal loss and decreased cases of congenital syphilis. We believe that the reduction of stillbirth and other adverse reproductive outcomes due to congenital syphilis constitutes a valuable outcome of preventive services in averting the profound and often incalculable human costs of intrauterine death and the expenditures to provide subsequent psychological and medical care.

CMS is also mindful that in its early and latent stages, a syphilis infection may remain asymptomatic and clinically undetected both in women of child -bearing age and in older persons. Risk-based screening strategies are therefore based on studies showing that a variety of factors are associated with increased risk, including age-related decreased use of barrier protection during sex (Reece et al. 2010); increased potential that older men using drugs for erectile dysfunction (Jena et al. 2010); increased association of widowhood with STI diagnosis among older women (Smith and Christakis 2009). CMS believes these studies suggest that certain persistent behaviors in a minority of older persons increase their risk for all STIs and in particular argue in support of screening services for syphilis and other STIs in older beneficiaries, a subgroup of whom will, given available treatment, benefit from early diagnosis and treatment and will thus avoid later stages of syphilis infection (CDC 2010B).

*After careful review of the available body of evidence, we conclude that screening all pregnant women and all women and men at increased risk for STIs for syphilis provides improved outcomes in the prevention or early detection of illness or disability.*

*Is the evidence sufficient to determine that screening all pregnant women for syphilis and all women and men at increased risk for syphilis is appropriate for Medicare beneficiaries?*

We note that syphilis screening is appropriate in that it would address a potential need of sexually active persons enrolled in Part B of the Medicare program, including women of child-bearing ages and sexually active older individuals of both genders, even if these subgroups represent a relatively minor fraction of those enrolled in Part B of the Medicare program. Individuals eligible to enroll in Medicare Part B for whom this screening preventive service might be appropriate would potentially include those covered due to a qualifying disabling condition or those with end-stage renal disease.

As noted in the prior section, the benefits of early detection of syphilis are not confined to younger beneficiaries. Lindau 2007 informs that older beneficiaries remain sexually active even into the eighth and ninth decades of life (Lindau et al. 2007). CDC surveillance information shows the risk of STIs is present in the over 65 population as well as in younger individuals (CDC Summary of Notifiable Diseases 2008, Table 3, p. 32 (published 2010)). In fact, CDC data show that syphilis infection is the most frequent STI reported in the US among persons 65 years of age and older. (*idem*)

Given that the risk of syphilis has no upper age limit, CMS concludes that the benefits of screening for syphilis STI are generalizable to the older as well as younger Medicare population.

*After careful review of the available body of evidence, we conclude that screening all pregnant women and all men and women at increased risk for syphilis is appropriate for Medicare beneficiaries.*

***Hepatitis B***

*Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit is recommended with a grade of A or B by the USPSTF?*

USPSTF Summary of Recommendations for hepatitis B virus infection (2009)
"The USPSTF recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit. Grade: A Recommendation."

*CMS concludes that screening all pregnant women for hepatitis B at the first prenatal visit is recommended with a grade of A or B by the USPSTF.*

*Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit provides improved outcomes in the prevention or early detection of illness or disability?*

CMS recognizes the major importance of preventing perinatal transmission of hepatitis B virus infections, which according to CDC data account for 30 – 40% of cases of CHB in the US. Each case of perinatal hepatitis B virus infection may over time progress to serious and potentially life-threatening complications including cirrhosis, liver failure or HCC.

CMS notes that the benefits of screening and treatment for early detection of hepatitis B apply (although in different ways) both to the person being screened as well as to others at potential risk. In this case, the benefits include secondary prevention of complications of CHB, such as cirrhosis and liver failure, as well as decreased expenditures that result when the need to treat illnesses in others (such as infants with chronic hepatitis B) is avoided. There may be unquantifiable benefits to screened person who are HBsAg (+) (such as altering medical management during oncologic therapy) and HBsAg (-) (such as being identified as possible candidates for hepatitis B vaccination).

CMS notes that a recent expert consensus group issued guidelines on the management of hepatitis B in children (Haber et al. 2009). These guidelines suggested that for children with hepatitis B, appropriate steps would include testing, evaluation by a pediatric hepatitis B specialist, and potentially treatment with several agents available for children with hepatitis B. Such extensive medical workup, while valuable for secondary prevention of possibly serious sequelae of CHB during later life, would require substantial expenditures for the child's responsible party, an expenditure that HBsAg screening as recommended herein may help prevent.

*After careful review of the available body of evidence, we conclude that screening all pregnant women for hepatitis B at the first prenatal visit provides improved outcomes in the prevention or early detection of illness or disability.*

*Is the evidence sufficient to determine that screening all pregnant women for hepatitis B at the first prenatal visit is appropriate for Medicare beneficiaries?*

We note that women of child-bearing ages for whom this screening preventive service would be appropriate represent a small fraction of those enrolled in Part B of the Medicare program. Women eligible to enroll in Medicare Part B for whom this screening preventive service might be appropriate would potentially include those covered for a qualifying disabling condition or those with end-stage renal disease.

CMS believes that early detection of CHB due to screening for HBsAg in pregnant women provides an opportunity for appropriate interventions to benefit the infected mother. We also believe that the timing of such interventions in late adolescent or early adult life would modify the cumulative effect of CHB-mediated liver damage, which otherwise leads to cirrhosis and hepatocellular carcinoma in later adult life.

*After careful review of the available body of evidence, we conclude that screening all pregnant women for hepatitis B at the first prenatal visit is appropriate for Medicare beneficiaries.*

***HIBC for the prevention of STIs***

*Is the evidence sufficient to determine that HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs is recommended with a grade of A or B by the USPSTF?*

USPSTF Summary of Recommendations for behavioral counseling to prevent sexually transmitted infections (2008)
"The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs. Grade:  B recommendation."

*CMS concludes that HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs is recommended with a grade of A or B by the USPSTF.*

*Is the evidence sufficient to determine that HIBC to prevent STIs for all sexually active adolescents and for all adults at increased risk for STIs provides improved outcomes in the prevention or early detection of illness or disability?*

Based on published meta-analyses, CMS acknowledges the demonstrated efficacy of high-intensity behavioral counseling interventions to prevent STIs. We believe that the evidence presented in the systematic reviews and evidence assessments summarized above indicate the efficacy of such interventions for decreasing risky behavior and STD incidence. Recent evidence from Carey 2010 and Semaan 2010 is consistent with prior studies such as Kamb 1998 in showing reduced STI incidence and decreased risky behaviors among intervention participants.

While the USPSTF did not specifically define HIBC, the evidence that supported their recommendation portrayed counseling interventions that included a single 4-hour session, three 1-hour sessions over 3 consecutive weeks, four 4-hour sessions, and a 10 sessions. However, they also mentioned a study that found benefit from a single, 20 minute session delivered in a primary care setting (USPSTF 2008). Lin et al. described high intensity as "multiple-visit interventions requiring more than 2 hours in total (Lin et al. 2008)." Kamb et al. looked at the efficacy of risk-reduction counseling to prevent HIV and STDs and concluded that short counseling interventions using personalized risk reduction plans increased barrier protection use and prevented new STDs.

The preponderance of the evidence that supported the USPSTF recommendation looked at studies that included programs that were judged to be feasible in primary care settings and included elements of education, skills training, and guidance on how to change sexual behavior intended to promote sexual risk reduction or risk avoidance. CMS believes that the evidence for HIBC supporting improved outcomes is inherently linked to the primary care setting in that USPSTF makes recommendation for services in the primary care setting. We also believe the systematic, patient-focused content of the counseling interventions establishes the high intensity of the counseling rather than the number or duration of interventions. This is supported by the outcomes of benefit identified by Kamb 2008. Therefore, based on the evidence we define HIBC to prevent STIs as a counseling program focused on promoting sexual risk reduction or risk avoidance that includes the following broad elements, with the flexibility to be systematic and patient-focused: elements of education, skills training, and guidance on how to change sexual behavior, and provided by a primary care provider in the primary care setting.

*After careful review of the available body of evidence, we conclude HIBC for all sexually active adolescents and all adults at increased risk for STIs provides improved outcomes in the prevention or early detection of illness or disability.*

*Is the evidence sufficient to determine that HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs is appropriate for Medicare beneficiaries?*

We note that HIBC appropriately addresses a need of sexually active persons enrolled in Part B of the Medicare program, including adolescents who are sexually active and individuals at high risk. Individuals eligible to enroll in Medicare Part B would potentially include those covered due to a qualifying disabling condition or those with end-stage renal disease, in addition to senior beneficiaries; for some of these beneficiaries, this preventive service will be appropriate.

CMS is convinced that HIBC provides a benefit in the reduction of high risk sexual behaviors and prevention of STIs. However, we note that the preponderance of the published clinical trials included the adolescent and young adult population. This population is not sufficiently representative of the Medicare population to convince us that the range of frequency of counseling sessions identified in the available clinical trials are directly generalizable to the core Medicare population. However, we are convinced that benefits of appropriate patient-focused sexual risk reduction counseling are generalizable to the Medicare population if the counseling is structured to an older/adult population.

We believe the counseling would be most effective when delivered individually in a face to face meeting with the primary care provider within the primary care setting. The counseling must be provided within a structured program intended to promote sexual risk reduction or risk avoidance that contains all of the following broad elements systematically applied and tailored to patient needs: education, skills training, and guidance on how to change sexual behavior. These are the same elements of the counseling programs that were used in the clinical trials that supported the USPSTF recommendation. The HIBC program documentation should be maintained at the primary care setting that is providing the counseling. CMS believes that a structured HIBC program can be effectively delivered in two individual 20 to 30 minute face to face sessions which is consistent with the Kamb 2008 conclusion.

We notice that in studies such as Sznitman 2010, interventions crafted to apply to the special needs of traditionally underserved populations are also shown to be effective. We encourage further research that may address the use of this and other STI reduction interventions to the elimination of racial and ethnic disparities.

*After careful review of the available body of evidence, we conclude that HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs is appropriate for Medicare beneficiaries*.

**Primary Care and USPSTF Recommended Preventive Services**

CMS believes the primary care setting and the primary care provider is integral in the coordination of preventive services. The USPSTF recommendations are for preventive services that should be provided in the primary care setting (AHRQ *2010 – 2011 USPSTF Preventive Services Guide*). Preventive services should be provided within the context of a coordinated prevention plan based on the individual patient's needs assessed over time through the ongoing relationship established with the primary care provider. The IOM provides a definition of primary care (IOM. *Primary Care: America's Health in a New Era* 1996) and existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)) further defines primary care practitioners. The IOM further identifies one of the values of primary care as the opportunity for disease prevention and health promotion.

Based on the charge of the USPSTF in evaluating services provided in the primary care setting, CMS concludes referrals for the USPSTF recommended screenings for chlamydia, gonorrhea, syphilis and hepatitis B for the specific populations should be made by the primary care provider in the primary care setting. CMS also feels that the IOM definition of primary care and the role of primary care in disease prevention and health promotion certainly supports that the risk assessment and referral for these screening services is best coordinated by the primary care provider in the primary care setting. In addition, the USPSTF research that supported the recommendation for HIBC for the prevention of STIs looked at clinical trials that were performed in primary care setting or that could be performed in the primary care setting.

CMS concludes that the effective and efficient utilization of these screening tests are best coordinated by the primary care provider and based on an evaluation of the patient's sexual history which is part of a comprehensive medical history typically documented during an annual wellness visit or prenatal visit. CMS further concludes that evidence supporting the use HIBC for the prevention of STIs is linked to the primary care setting and should be provided within the context of a comprehensive prevention plan developed by the primary care provider.

**Cost Considerations for Screening for STI and HIBC for cost prevention**

A review of available literature revealed that studies of the cost burden of STIs and their consequences indicate substantial opportunities for economic as well as disease prevention benefit to society resulting from improved STI prevention. However, a lack of a consistent system of cost accounting for outpatient clinic screening and prevention services, as well as a lack of standard methods for cost accounting, led to concerns that cost estimates from the few such studies suffer from heterogeneity both in their methods and their findings. We conclude that findings from studies about effects of STI screening and prevention programs such as HIBC on expenditures would be difficult to generalize. In addition, no studies focused on non-reimbursed out-of-pocket expenditures by screened individuals for screening and prevention services.

While §410.64(b) allows the Secretary to conduct an assessment of the relation between predicted outcomes and the expenditures for such services and to take the results of such an assessment into account in making an NCD, for this review the evidence is insufficient to perform an informative analysis. Without sufficient evidence to support stronger conclusions about impact of screening programs on expenditures, we are nevertheless persuaded that in view of its relatively low cost per STI prevented (eg, Schalm 1989), especially in high-risk populations as defined above, STI screening and prevention programs including HIBC offer attractive options for STI control. Treatment of identified infections does provide the opportunity for the avoidance of future complications from the infections which would require utilization of more intensive health resources. HIBC for the prevention of STIs provides improvement in the behavioral risk factors associated with STIs and the potential for avoidance of future STIs and the utilization of resources associated with those infections. However, CMS recognizes that this area represents a gap in evidence and encourages additional studies of the effects of STI screening and prevention programs such as HIBC on expenditures in beneficiary populations.

***Disparities in STIs***

"Improving health care disparities is an integral part of improving health care quality (AHRQ Healthcare Disparities Report, 2008)."

The CDC report, *Trends in Sexually Transmitted diseases in the United States: 2009 National Data for Gonorrhea, Chlamydia and Syphilis* (November 2010), addresses the disparities by race and age in the occurrence STDs (gonorrhea, chlamydia and syphilis).

"CDC surveillance data show much higher rates of reported STDs among some racial or ethnic minority groups than among whites. This is consistent with other data sources showing marked STD disparities in some minority populations. A range of factors contributes to these disparities, including poverty, lack of access to health care and an already high prevalence of STDs in communities of color that increases a person's risk of infection with each sexual encounter. And regardless of race or gender, data show that sexually active adolescents and young adults are at increased risk for STDs when compared to older adults. Acknowledging disparities in STD rates is one of the first steps in empowering affected communities to focus on the problem and helping the public health community direct prevention and treatment resources appropriately (CDC – Trends in Sexually Transmitted Diseases in the United States: 2009 National Data for Gonorrhea, Chlamydia and Syphilis 2010)."

Table from *Trends in Sexually Transmitted diseases in the United States: 2009 National Data for Gonorrhea, Chlamydia and Syphilis* (November 2010).

| **Disparities**<br>A range of factors contribute to STD disparities by race/ethnicity, including: a greater prevalence of STDs in minority communities, which places individuals living in those communities at increased risk of infection with each sexual act, compared to other populations; poverty; lack of access to quality healthcare; and stigma and homophobia, which can prevent individuals in need from seeking STD prevention, screening and treatment services. | | |
|---|---|---|
| • Blacks accounted for 71% of all gonorrhea cases in 2009, though they represent only 14% of the U.S. population. The gonorrhea rate among blacks is 20 times higher than whites and almost 10 times higher than Hispanics (556.4 per 100,000 for blacks v. 27.2 for whites and 58.6 for Hispanics). | • Blacks represented almost half of all reported Chlamydia cases (48%) in 2009. Based on case reports, the Chlamydia rate among blacks is eight times higher than whites and three times higher than Hispanics (1,559.1 per 100,000 for blacks v. 178.8 for whites and 504.2 for Hispanics). | • Since 2000, the largest increase in syphilis cases has been among men who have sex with men (MSM). In 2009, MSM accounted for nearly two-thirds of syphilis cases (62%), up from just 4% in 2000.<br><br>• Blacks accounted for half of all P&S syphilis cases (52%) in 2009. The rate of P&S syphilis among blacks is nine times higher than whites and four times higher than Hispanics (19.2 per 100,000 for blacks v. 2.1 for whites and 4.5 for Hispanics). |

| | | |
|---|---|---|
| • **Young black women** bear the heaviest gonorrhea burden (rate among those aged 15-19: 2,613.8 per 100,000; rate among those aged 20-24: 2,548.7 per 100,000). | • **Young black women** aged 15-24 are most affected. In 2009, there was one Chlamydia case reported for every 10 black women in that age group (10,629.7 per 100.000). | • P&S syphilis cases among young black men aged 15-24 continue to increase significantly – indicating a concerning new trend. Between 2005 and 2009, the P&S syphilis rate among **young black men** aged 15-24 tripled (from 19.3 per 100,000 in 2005 to 58.2 in 2009). This trend may also be contributing to disproportionately high rates of HIV among young black men. |
| • **Young Hispanic women and men** aged 20-24 have the highest gonorrhea rates among Hispanics, which are twice as high as those among whites in the same age group (In the 20-24 age group: 274.9 per 100,000 for Hispanic women v. 186.4 for white women; 215.7 per 100,000 for Hispanic men v. 80.8 for white men). | • **Young Hispanic women and men** aged 20-24 have the highest Chlamydia rates among Hispanics, which are twice as high as those among whites in the same age group (In the 20-24 age group: 3,679.7 per 100,000 Hispanic women v. 1,727.8 for white women; 1,077.8 per 100, Hispanic men v. 491.9 for white men). | |

In addition, despite the overall success in the public health campaign against viral hepatitis, "there remain racial, ethnic, and socioeconomic disparities in the incidence and prevalence of acute and chronic viral hepatitis, the outcomes of chronic viral hepatitis, and health care access and quality (El-Serag, et al. 2010)." "Minority populations in the United States are disproportionately affected by acute and chronic viral hepatitis. For example, African Americans bear a disproportionate burden of new hepatitis B virus (HBV) infections, with an incidence of 2.2 cases/100,000 population in 2007. This is higher than all other racial and ethnic groups. The prevalence of HBV infection among African Americans is also higher than among whites…(El-Serag, et al. 2010)."

As stated in the National Plan for Action, from the National Partnership for Action, " Beyond the heavy burden that the health and healthcare disparities represent for the individuals affected, there are additional social and financial burdens borne by the country as a whole. These burdens constitute both ethical and practical mandates to reduce health disparities and achieve health equity (The National Plan for Action Draft as of February 17, 2010 )."

**Summary**

STIs continue to be problematic in the United States with both health and economic consequences. The USPSTF reviewed the available evidence and provided an A or B recommendation in certain circumstances for screening for chlamydia, gonorrhea, syphilis and hepatitis B. CMS reviewed the USPSTF recommendations and performed its own review of the evidence. The evidence supported that screening for the USPSTF indicated STIs provided improved health outcomes in certain populations by allowing for the appropriate treatment and/or medical management. Reference to high/increased risk, as described by the USPSTF, is defined in section VII.D of this document.

Screening for chlamydia, gonorrhea and syphilis infections provides a direct benefit to the Medicare beneficiary by allowing for the treatment of existing infections and preventing future health consequences of the disease and utilization of health resources to treat these consequences.

Screening for hepatitis B provides benefit to the mother (Medicare beneficiary) by providing for the early detection of the disease which allows for the monitoring and appropriate medical management for acute or CHB as it develops. Screening for HBV, as for the other STIs, has the added public health benefit of identifying Medicare beneficiaries who are infected with the HBV and, through information and education to change high risk behaviors, reducing the transmission of STIs to sexual partners. Screening also helps in identifying HBsAg negative beneficiaries who need to be vaccinated as a prevention measure.

CMS concludes that FDA approval/clearance of screening tests used consistent with the FDA approved label provides a greater likelihood that a potential harm of screening testing, that is, taking action based on inaccurate screening test results, can be avoided. We further conclude that compliance by testing laboratories with CLIA regulatory requirements provides an additional, on-going safeguard for screening test quality. CMS considers these conditions essential to maximize patient safety.

A sexual history is part of any patient’s complete medical history taken during a health care visit, such as an annual wellness visit, or prenatal visit and should be considered in evaluating the patient’s risk factors in developing a comprehensive prevention plan. A determination of risk should be made at the time the sexual history is taken and appropriate referrals for screening made at that time. Since the risk factors are similar for all the STIs under consideration, screening for STIs should be clustered when possible.

The USPSTF identified intervals for testing for chlamydia and gonorrhea in high risk pregnant women were at the first prenatal visit and repeat screening in the third trimester if high risk sexual behavior had continued since the first screening. Screening for syphilis in pregnant women was recommended by USPSTF at the first prenatal visit and retesting during the third trimester and at delivery for women with new or continued high risk sexual behaviors. The USPSTF recommended screening for hepatitis B at the first prenatal visit and mentioned that numerous organizations support retesting on admission to the hospital, birthing center, or other delivery setting for women with unknown HBsAg or with new or continued high risk sexual behaviors. While the USPSTF was unable to find any evidentiary support for specific intervals of testing for the high risk, non pregnant populations recommended for screening, it was noted that the CDC recommended annual screening for chlamydia. Since non pregnant women at increased risk for chlamydia would also be at increased risk for gonorrhea and syphilis, and STI testing is usually clustered during an annual periodic primary care visit, CMS supports annual screening for all the USPSFT recommended STI screenings reviewed in this document for this population. For high risk men, CMS also supports annual screening for syphilis.

In addition, the USPSTF has provided a B recommendation for HIBC for the prevention of STIs. The USPSTF and CMS review of the evidence showed a reduction in high risk sexual behaviors and rates of STIs after HIBC. The studies that supported the USPSTF recommendation included elements of education, skills training, and guidance on how to change sexual behavior intended to promote sexual risk reduction or risk avoidance. CMS believes the comprehensive and patient-focused content of the counseling interventions establishes the intensity of the counseling rather than the number or duration of interventions. CMS is convinced that HIBC for the prevention of STIs is appropriate for the Medicare population when the counseling is tailored for an older population. We believe the counseling would be most effective when delivered individually in a face to face meeting within the primary care setting. The counseling must be provided within a structured program intended to promote sexual risk reduction or risk avoidance that contains all of the following elements: education, skills training, and guidance on how to change sexual behavior. Most of the studies involved a younger population who are not necessarily CMS beneficiaries. This population is not sufficiently representative of the Medicare population to convince us that the frequency of counseling sessions provided in the programs reviewed in the available clinical trials is directly generalizable to the core Medicare population. However, we are convinced that benefits of sexual risk reduction counseling are generalizable to the Medicare population if the counseling is structured to an older population. CMS believes that a structured HIBC program can be effectively delivered in up to two individual - 20 to 30 minute face to face sessions annually when referred for this service by a primary care provider and provided by a primary care provider within the primary care setting.

The USPSTF recommended both the patient's modifiable behaviors (individual risk factors) and nonmodifiable demographics and social situation should be considered by the physician in determining risk for STIs. Examples of individual risk factors were identified as multiple sex partners, using barrier protections inconsistently, having sex under the influence of alcohol or drugs, having sex in exchange for money or drugs, age for women (24 years of age or younger and sexually active), having had an STI within the past year, IV drug use (for hepatitis B only), and, in addition for men – MSM and engaged in high risk sexual behaviors, but no regard to age. The USPSTF recommended that physicians also use community social factors that increase STI risk as surrogate markers in determining risk for STI screening. In addition, USPSTF stated, "Rather than considering each recommendation separately, physicians can cluster STI screening at the time of a periodic health examination (USPSTF Recommendations for STI Screening and Behavioral Counseling to Prevent STIs)."

USPSTF is tasked with evaluating services that should be provided in the primary care setting. So their recommendations for screenings for STIs and for HIBC are based on providing of these services in the primary care setting. Lin's systematic review looked at trials that evaluated behavioral counseling interventions conducted in primary care or judged to be feasible in primary care settings (Lin et al. 2008). So the conclusions of benefit from the HIBC came from studies related to the primary care setting. Additionally, risk assessment for referral for STI screenings and/or HIBC is determined from the sexual history of the individual which is part of any complete medical history taken at the time of a periodic exam or prenatal visit typically provided in the primary care setting. Screening laboratory tests for STIs would require an order from the physician evaluating the risk factors. CMS believes that the primary care setting is the optimum setting for evaluating risk for STIs and referring for appropriate screenings, counseling and treatment if necessary. This is consistent with the USPSTF recommendations and with the definition of the function of primary care provided by the IOM which states; "Primary care is the provision of *integrated, accessible health care services* by clinicians who are *accountable* for addressing a large majority of personal health care needs, developing a *sustained partnership with patients*, and practicing in the *context of family and community* (IOM *Primary Care: America's Health in a New Era*. 1996). Further, in discussing the value of primary care, one of the elements cited supporting this definition is that primary care "…opens opportunities for disease prevention and health promotion as well as early detection of disease… (IOM*Primary Care: America's Health in a New Era* 1996)." We believe that the providers who meet this definition of the function of primary care are identified in the Social Security Act in two existing sections: in section 1833(u)(6) which defines primary care providers as, '…a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist."; in section §1833(x)(2)(A)(i)(I), which defines a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; and in section §1833(x)(2)(A)(i)( (II), which adds a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)). CMS is convinced that the primary care setting is essential for coordinating the most efficient use of health resources by optimizing the effective use of preventive services through the development of a comprehensive prevention plan that would lead to the appropriate recommendation for screening for STIs and for HIBC for the prevention of STIs.

**IX. Conclusion**

The evidence is adequate to conclude that screening for chlamydia, gonorrhea, syphilis and hepatitis B, as well as HIBC to prevent STIs, consistent with the grade A and B recommendations by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore, CMS will cover screening for these USPSTF indicated STIs with the appropriate FDA approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with CLIA regulations, when ordered by the primary care physician or practitioner, and performed by an eligible Medicare provider for these services,

- Screening for chlamydia and gonorrhea:
  - Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.
  - Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.
  - Women at increased risk for STIs annually.

- Screening for syphilis:
  - Pregnant women when the diagnosis of pregnancy is known and then repeat screening during the third trimester and at delivery if high risk sexual behavior has occurred since the initial screening test.
  - Men and women at increased risk for STIs annually.

- Screening for hepatitis B
  - Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known and then rescreening at time of delivery for those with new or continuing risk factors.

CMS will also cover up to two individual 20 to 30 minute, face to face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs, if referred for this service by a primary care provider and provided by a Medicare eligible primary care provider in a primary care setting. Coverage of HIBC to prevent STIs is consistent with the USPSTF recommendation. HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:

- education,
- skills training,
- guidance on how to change sexual behavior.

The high/increased risk individual sexual behaviors, based on the USPSTF guidelines, include any of the following:

- Multiple sex partners
- Using barrier protection inconsistently
- Having sex under the influence of alcohol or drugs
- Having sex in exchange for money or drugs
- Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea)
- Having an STI within the past year
- IV drug use (for hepatitis B only)
- In addition for men – men having sex with men (MSM) and engaged in high risk sexual behavior, but no regard to age

In addition to individual risk factors, in concurrence with the USPSTF recommendations, community social factors such as high prevalence of STIs in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis and for recommending HIBC.

High/increased risk sexual behavior for STIs should be determined by the primary care provider by assessing the patient's sexual history which is part of any complete medical history, typically part of an annual wellness visit or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this decision memorandum, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

For the purposes of this decision memorandum, a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));

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# Draft

# Medicare National Coverage Determinations Manual

# Chapter 1, Part 4 (Sections 200 – 310.1)

## Coverage Determinations

## Table of Contents



***210.10 – Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to prevent STIs (Rev. )***

***A. General***

*Sexually transmitted infections (STIs) are infections that are passed from one person to another through sexual contact. STIs remain an important cause of morbidity in the United States and have both health and economic consequences. Many of the complications of STIs are born by women and children. Often, STIs do not present any symptoms so can go untreated for long periods of time. The presence of an STI during pregnancy may result in significant health complications for the woman and infant. In fact, any person who has an STI may develop health complications. Screening tests for the STIs under consideration in this NCD are laboratory tests.*

*Under §1861(ddd) of the Social Security Act, CMS has the authority to add coverage of additional preventive services if certain statutory requirements are met. Our regulations provide:*

*§410.64 Additional preventive services*

*(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:*

*(1) Reasonable and necessary for the prevention or early detection of illness or disability.*
*(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.*
*(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.*

*(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.*

*The scope of the national coverage analysis for this national coverage determination evaluated the evidence for the following STIs and high intensity behavioral counseling (HIBC) to prevent STIs for which the United States Preventive Services Task Force (USPSTF) has issued either an A or B recommendation:*

- *Screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older nonpregnant women who are at increased risk,*
- *Screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk,*
- *Screening for gonorrhea infection in all sexually active women, including those who are pregnant, if they are at increased risk,*
- *Screening for syphilis infection for all pregnant women and for all persons at increased risk,*
- *Screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit,*
- *HIBC for the prevention of STIs for all sexually active adolescents and for adults at increased risk for STIs.*

***B. Nationally Covered Indications***

*CMS has determined that the evidence is adequate to conclude that screening for chlamydia, gonorrhea, syphilis and hepatitis B, as well as high intensity behavioral counseling (HIBC) to prevent STIs, consistent with the grade A and B recommendations by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the early detection or prevention of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.*

*Therefore, effective for claims with dates of services on or after November XX, 2011, CMS will cover screening for these USPSTF indicated STIs with the appropriate FDA approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the primary care physician or practitioner, and performed by an eligible Medicare provider for these services.*

- *Screening for chlamydia and gonorrhea:*

- *Pregnant women who are 24 years old or younger when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.*
- *Pregnant women who are at increased risk for STIs when the diagnosis of pregnancy is known and then repeat screening during the third trimester if high risk sexual behavior has occurred since the initial screening test.*
- *Women at increased risk for STIs annually.*

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*Screening for syphilis:*
- *Pregnant women when the diagnosis of pregnancy is known and then repeat screening during the third trimester and at delivery if high risk sexual behavior has occurred since the previous screening test.*
- *Men and women at increased risk for STIs annually.*

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*Screening for hepatitis B:*
- *Pregnant women at the first prenatal visit when the diagnosis of pregnancy is known and then rescreening at time of delivery for those with new or continuing risk factors.*

*In addition, effective for claims with dates of service on or after November XX, 2011, CMS will cover up to two individual 20 to 30 minute, face to face counseling sessions annually for Medicare beneficiaries for HIBC to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs, if referred for this service by a primary care provider and provided by a Medicare eligible primary care provider in a primary care setting. Coverage of HIBC to prevent STIs is consistent with the USPSTF recommendation. HIBC is defined as a program intended to promote sexual risk reduction or risk avoidance which includes each of these broad topics, allowing flexibility for appropriate patient-focused elements:*

- *education,*
- *skills training,*
- *guidance on how to change sexual behavior.*

***The high/increased risk*** individual sexual behaviors, based on the USPSTF guidelines, include any of the following:

- *Multiple sex partners*
- *Using barrier protection inconsistently*
- *Having sex under the influence of alcohol or drugs*
- *Having sex in exchange for money or drugs*
- *Age (24 years of age or younger and sexually active for women for chlamydia and gonorrhea)*

- *Having an STI within the past year*
- *IV drug use (for hepatitis B only)*
- *In addition for men – men having sex with men (MSM) and engaged in high risk sexual behavior, but no regard to age*

*In addition to individual risk factors, in concurrence with the USPSTF recommendations, community social factors such as high prevalence of STIs in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis and for recommending HIBC.*

*High/increased risk sexual behavior for STIs is determined by the primary care provider by assessing the patient's sexual history which is part of any complete medical history, typically part of an annual wellness visit or prenatal visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.*

*For the purposes of this NCD, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.*

*For the purposes of this NCD, a "**primary care physician**" and "**primary care practitioner**" will be defined based on existing sections of the Social Security Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).*

*§1833(u)*
*(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.*

*§1833(x)(2)(A)(i)*
*(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or*
*(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));*

***C. Nationally Non-Covered Indications***
*Unless specifically covered in this NCD, any other NCD, or in statute, preventive services are non covered by Medicare.*

***D. Other***
*Medicare coinsurance and Part B deductible are waived for this preventive service. Only one HIBC service should be provided on the same date of service.*

*HIBC may be provided on the same date of service as an annual wellness visit, E&M visit or during the global period for obstetrical care. See the claims processing manual for complete claims processing instructions.*

***(This NCD last reviewed November 2011.)***

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